The importance of risk-stratification in colorectal surgery

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THE IMPORTANCE OF RISK-STRATIFICATION IN COLORECTAL SURGERY

Results of the Zaandam audit

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THE IMPORTANCE OF RISK-STRATIFICATION IN COLORECTAL SURGERY

Results of the Zaandam audit

academisch proefschrift

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door

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CONTENTS

INTRODUCTION

1.1 GENERAL INTRODUCTION

Improving the quality of care is an important part of surgical practice, and the audit has thus become a routine and essential part of surgical practice.
The outcome of surgery is of increasing interest to health authorities, insurance companies and patients, and a considerable media interest has been directed in recent years toward a comparison of performance of individual hospitals and surgeons.
The outcome of surgery cannot, however, be measured by crude post-operative in-hospital or 30-day mortality figures but is a result of multiple factors that are provider, disease, and patient related. For providers, hospitals as well as surgeons, it is expected that volume, experience, certification, and quality of perioperative care play an important role.
Disease-related factors would include high-risk complex operations or rare diseases, which probably are better treated in specialized centers. Patient-related major factors in the outcome are the physiologic status and comorbidity of the patient. This insight has led to a growing interest in, and discussion and study of the factors, or combination of factors, that are important in the outcome of surgical care.
In the United States of America (USA), this lead to the volume-outcome discussion, especially stimulated by the Leapfrog initiative, in which several large employers and health-care purchasers combined to leverage improvements in health care. To care for Leapfrog employees, hospitals were required to meet various standards. At the start, the safety standards required volume standards for five selected high-risk procedures as well as neonatal intensive care in addition to computerized order entry by physicians and intensive care units staffed by full time intensivists [1].
Because many criticized the standards for focusing only on procedure volume, they were revised in 2003. Some volume standards were replaced by quality measures based on processes of care and/or patient outcome. Volume standards were required only for pancreatic resection and esophagectomy. For elective abdominal aortic aneurysm repair, both volume standards and process measures were demanded [2].
The volume-outcome discussion is not limited to the procedures chosen by the Leapfrog group. In colorectal surgery discussion is also ongoing regarding the possible effects of hospital volume and/or surgeon volume and surgeon certification as well on the direct post-operative mortality. Several authors in

this surgical specialty found that both hospital volume and surgeon volume were independent factors with an inverse effect on post-operative mortality in colon resection. Higher-volume providers had about 2% lower post-operative mortality.

For colon carcinoma, Ko *et al.* (2002) [3] found that both hospital volume and surgeon volume were significant factors in acute or elective partial colectomy with an inverse relation with in-hospital death. The same was reported by Hannan *et al*. (2002) [4] in a comparable group of patients.

In their series, the correlation between hospital volume and surgeon volume was reasonably high. Also evident was an interaction between surgeon and hospital volume: high-volume surgeons in low-volume hospitals had worse results than their counterparts in high-volume hospitals, and low-volume surgeons in high-volume hospitals also had poorer results.

Harmon *et al.* (2002) [5] had already described this in acute or elective surgery for colorectal cancer. Partial or total colectomy, and abdominal perineal resection and anterior resection were included in their group of patients. Hospital volume could, to a certain extent, serve as a surrogate for surgeon volume.

Khuri *et al*. (1999) [6], however, found no statistical significant association between hospital volume (both the procedure and the surgical specialty levels) and the risk-adjusted 30-day mortality rate in patients who underwent an acute or elective partial colectomy for all indications.

Halm *et al*. (2000) [7] systematically reviewed the methodological rigor of the research on volume and outcome for a variety of surgical and nonsurgical procedures and summarized the magnitude and significance of the differences.

They concluded that the literature was too heterogeneous to permit a formal quantitative meta-analysis and that the magnitude of the volume-outcome association varied greatly by topic. Nevertheless, they concluded that the evidence supported the general proposition that higher volume is associated with better outcomes, although the consistency and magnitude of the relationship varied greatly. The most consistent and striking absolute differences in mortality rates were found between high-volume and low-volume hospitals for pancreatic cancer surgery, esophageal cancer surgery, pediatric cardiac surgery, treatment of AIDS, and elective surgery for abdominal aortic aneurysm. In surgery for colorectal cancer, surgeon volume seemed to be a more important determinant of outcomes than hospital volume.

Hodgson *et al.* (2001) [8] reviewed the literature regarding the relation between patient and provider characteristics and outcomes of the surgical treatment of colorectal cancer.

They concluded that surgeon experience has been related most consistently to

outcomes that measure tumor control, such as a better local control or cancer-specific survival. In some reports, surgeon or hospital volume has been associated with a greater change of sphincter preservation. Although some studies have reported an association between provider characteristics and post-operative mortality or overall mortality, these findings were not consistent.
Some studies in the USA have also been published on the relation between colorectal surgery outcome and certification. Surgeons who are certified by the American Board of Surgery (ABS) and increasing surgeon experience were factors associated with reduced post-operative mortality and morbidity in patients who underwent acute or elective partial colectomy for carcinoma as described by Prystowsky *et al.* (2002) [9]. Total colectomy and rectal surgery were excluded in their series.
However, neither colorectal surgery certification by the ABS nor site of residency training significantly affected outcomes in this study.
Callahan *et al.* (2003) [10] concluded that membership in the Society of Surgical Oncology or the Society of Colorectal Surgery was an independent factor for lower in-hospital mortality in colectomy patients. Their report did not, however, define the type of operation nor was the urgency of admission or colon pathology included in the risk-analysis.
In general, it can be said that a crude relation exists between volume and outcome that varies greatly among procedures and conditions. The strongest relation has been found for treatment of AIDS and surgery for pancreatic and esophageal cancer, elective abdominal aneurysm, and congenital heart disease. Less difference can be found in colorectal surgery.
Moreover, many reports can be criticized for the definition and ascertainment of surgical death, the quality and validation of the databases, the type of risk-adjustment, selection bias, the definition of low-volume versus high-volume or negative publication bias (Russell *et al.* in 2001, Finlayson *et al.* in 2002,Russell *et al.* in 2003, Bass *et al.* in 2004) [11-14].

In the United Kingdom (UK), the discussion was especially focused on the development of scoring systems for assessing a patient's risk of death or complications rather than on the volume-outcome hypothesis. Various scoring systems have been developed, but the Physiologic and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) scoring system, published by Copeland *et al.* in1991 [15], is the most promising of the currently available scores in general and colorectal surgery.
With the POSSUM score, a comparative audit of colorectal resection for all diagnoses and type of operation was proved possible between surgical units (Sagar *et al.*1994 [16]) as well as individual surgeons (Sagar *et al.* 1996 [17]).

Some authors criticized the original POSSUM equation because it overpredicted mortality in low-risk patient groups. Prytherch *et al.* [18] developed the p-POSSUM (Portsmouth-POSSUM) equation by using the same set of parameters as in the original score. However, Weijsinghe *et al.* [19], who compared the POSSUM and p-POSSUM scoring system as predictor for post-operative death after vascular surgery, concluded that different outcomes were caused by the use of inappropriate analysis of the mortality groups.
In a review on risk scoring in surgical patients in 1999, Jones and de Cossart [20] concluded that POSSUM is effective and is the most appropriate tool of the currently available scores for surgical audit in general surgery and also in specific groups such as patients with colorectal disease.
Neary *et al.* in 2003 [21] also reviewed the literature on the POSSUM method and concluded that when correctly used, POSSUM can usefully compare outcomes among surgeons and hospitals. In specialist surgery, individual regression equations may be needed for each index procedure.
However, Tekkis *et al.* (2003) [22] found in a large group of patients undergoing major elective or emergent colorectal surgery for malignant or nonmalignant disease that the POSSUM score and the p-POSSUM score underpredicted mortality in the elderly and acute group, whereas mortality in young patients was overpredicted.
This lack of calibration in subgroup analysis lead to the development by Tekkis *et al.* (2004) [23] of a dedicated risk-adjustment scoring system for colorectal surgery, the cr-POSSUM (colorectal-POSSUM) which requires now external validation.
This equation can be criticized because it was calculated in a group of patients of whom 36% had proctology procedures and 8% had abdominal operations other than colorectal.
Senagore *et al.* (2004) [24] evaluated the applicability of the POSSUM, p-POSSUM, and cr-POSSUM scoring system with a cohort of colon cancer patients operated on in the USA. All POSSUM equations overpredicted mortality. The cr-POSSUM appeared to be the most promising audit tool for colorectal surgery but still overpredicted mortality and will require further refinement.
Moreover, Bennett-Guerrero *et al.* (2003) [25] used the p-POSSUM equation to compare the predicted mortality risk in a large cohort of patients undergoing major noncardiac surgery in large university teaching hospitals in the USA and the UK. The predicted mortality in both groups was about the same. However, when the observed mortality in the UK matched the predicted one, the observed mortality in the USA appeared to be four times lower than the predicted one. This suggests that the p-POSSUM model also needs adjustment for specific countries or healthcare systems.
Until dedicated colorectal scoring systems have been developed the POSSUM and

p-POSSUM methodology currently stands comparison with other sophisticated methods of case-mix analysis and represent the benchmark for comparing newer predictive indices.

In The Netherlands, some research has been done to see if a relationship exists between volume and outcome in operations for pancreatic or esophageal cancer, with the advice that these operations be centralized [26-28]. No risk-adjusted figures were published to support this advice, however.
A growing discussion about certification of surgeons and surgical units for various diseases has also started and has been established in several subspecialties. However, no reliable results have been published since this change.
Nationwide randomized prospective trials with special training of participating surgeons and experienced supervisors in the operating room were supposed to improve the quality of the surgical procedure, similar to that which occurred in the Dutch randomized trial of D1 and D2 lymph node dissection for gastric cancer from 1989 to 1994 in which 62 % of the Dutch hospitals participated [29].
The Dutch Total Mesorectal excision (TME) trial from 1996 to 2000 used the same quality control, and 70% of the Dutch hospitals enrolled patients in the study [30].
These trials lead to a concentration of patients operated on by specialized surgeons, and in the case of the TME trial, with a far less percentage of local recurrence. It is not known if this lower percentage was the result of specialization or was caused by a change in the operative technique. No risk-adjusted mortality figures are available, but crude post-operative mortality figures for rectal resections (APR plus RR) did not change before or during the TME study.
Also in The Netherlands, a nationwide registration of mortality and morbidity after general surgery has been developed to provide a base for an audit. This system has not yet been implemented and is criticized because only the American Society of Anesthesiologists (ASA) classification is used as a risk-adjustment. A reliable quality standard does not exist.
Some evidence shows that in colorectal surgery, an adverse relation exists between hospital volume, surgeon volume, specialization, and the outcome of surgery. But mortality rates can only be used in a comparative audit when they are adjusted for case mix, patient risks, and after the completeness of the collected data has been validated. POSSUM and p-POSSUM models for risk-adjustment probably need adjustment but will remain the benchmark for comparative audit until something better is developed.

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1.2 DATABASE

From 1990 to 2002, a prospective computerized morbidity and mortality registration was completed for all patients admitted to the surgical wards by the author. Patients who underwent acute or elective surgery on the colorectum were identified.
The completeness of the mortality figures was validated by comparing them with the Dutch National Medical Registry (Prismant). The validity of the Prismant data collection has been the subject of a large national study in which a correct administrative coding was obtained in more than 95% of patients [1].
Our database had complete agreement between mortality numbers and only 0.4% difference in the number of colorectal resections performed. We identified 1604 patients. Patients who needed more than one operation in a new hospital admission were considered to be a new patient for every operation they underwent. This database is the basis of the studies presented in this thesis.
Table 1 shows the crude number and type of operations in male and female patients, with the crude mortality and morbidity figures. Table 2 shows the type and definition of the registration of complications.

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TABLE 1 Types and numbers of operations

Type of operation	No.	Male	Female	Mortality (%)	Morbidity (%)
Right hemicolectomy	229	98	131	6.1	41.0
Left hemicolectomy	59	33	26	5.1	54.2
Resection sigmoid	316	130	186	5.1	50.6
Anterior resection	117	57	60	6.8	56.4
Anterior resection TME	50	32	18	8.0	58.0
Colostomy after laparotomy	97	36	61	18.6	58.8
Hartmann procedure	225	108	117	20.9	67.6
Colostomy	28	13	15	21.4	50.0
Extended right hemicolectomy	9	4	5	11.1	66.7
Extended left hemicolectomy	9	4	5	0.0	44.4
Resection colon transversum	28	14	14	0.0	53.6
Rectum amputation	66	43	23	4.5	75.8
Resection flexura hepatica	1	0	1	0.0	0.0
Resection flexura lienalis	3	3	0	0.0	66.7
Ileocecal resection	87	37	50	6.9	33.3
Miscellaneous	34	18	16	17.6	52.9
Restore Hartmann	107	57	50	2.8	42.1
Restore loop colostomy	64	31	33	1.6	29.7
Enteroenterostomy	29	16	13	24.1	58.6
Correction colostomy	35	18	17	0.0	17.1
Sub or total colectomy	5	3	2	40.0	80.0
Wedge resection	6	3	3	16.7	50.0
Total	1604	758	846	9.1	50.3

TME = total mesorectal excision

TABLE 2 Types of registered complications

- Deep wound infection: lay open of the wound was mandatory
- Intra-abdominal abscess: confirmed by laparotomy or percutaneous drainage
- Anastomotic leak: confirmed by intraluminal contrast studies and/or laparotomy
- Bleeding or significant wound hematoma
- Pulmonary: confirmed by chest radiograph and/or mucous cultures
- Thrombosis and/or pulmonary emboli: confirmed by venography, duplex ultrasonography, or ventilation/perfusion scans
- Pressure ulcera
- Urinary tract: infections confirmed by urine cultures
- Cardiac: confirmed by electrocardiography, CK/CK-MB studies, or radiograph
- Central nervous system: confirmed by CT scan
- Sepsis: confirmed by blood cultures
- Miscellaneous
- Multiple organ failure

CK = creatine kinase; CT = computed tomography

1.3 RISK-ADJUSTMENT

Audits are becoming more important in surgical practice. If performances of surgeons and surgical units are to be compared than the first objective must be to define case-mix per surgeon and per surgical unit. Only then can surgical outcome, after correction for differences in case-mix, be compared between surgeons and surgical units. In-hospital mortality is often used as an outcome parameter but post-operative morbidity is also frequently used.

Numerous scores have been developed to predict outcome. Without being complete some of the scoring systems are:

The Parsonnet score and EuroSCORE evaluate outcome of cardiac surgery. The SCOUT (Surgical Complication Outcome) score has been developed for vascular surgery in general, whereas patients with a ruptured aneurysm of the abdominal aorta may be assessed with the Hardman criteria or the Glasgow Aneurysm Score.

In trauma the Trauma Score (TS) and Revised Trauma Score (RTS), the Glasgow Coma Score (GCS), the Injury Severity Score (ISS) and Trauma Injury Severity Score (TISS) have been widely used.

The prognosis of critically ill patients and patients in the intensive care unit can be predicted by the Apache I and Apache II (Acute Physiology And Chronic Health Evaluation) scores, the SAPS (Simplified Acute Physiological Scores), the MPM (Mortality Prediction Model), the OSF (Organ System Failure score), the AOSF (Acute Organ System Failure score), the MOF score (Multiple Organ Failure), the SSS (Sepsis Severity Score), the Sickness score, the twenty-four-hour intensive unit scoring system or TISS (Therapeutic Intervention Scoring System).

Patients with peritonitis or intra abdominal sepsis can be assessed with Hughes' score, the MPI (Mannheim Peritonitis Index) or the Surgical Infection Stratification System for Intra abdominal Infection.

The score developed by the American Society of Anaesthesiologists (ASA score) has been widely used and tested in all types of surgery.

The Ranson score was developed for patients with acute pancreatitis and Child's classification evaluates the severity of liver failure.

Recently the Association of Colo-proctology of Great Britain and Ireland has developed a score (ACPGBI-CRC) for the prediction of in-hospital mortality after surgery for colorectal cancer.

However most, if not all, of these scores have been primarily developed in specific diseases or specific situations to predict outcome or to define treatment options.

In general these scores have not been designed with audit in mind. Very few scoring systems have been primarily designed for medical audit. One of these is the Physiologic and Operative Severity Score for the enUmeration of Mortality and morbidity scoring system (POSSUM).
Introduced by Copeland *et al.*[1] in 1991 the POSSUM score was devised as a simple scoring system. It was to be used, across the general surgical spectrum, for the purpose of surgical audit. It uses a two part scoring system with a physiological score (PS) containing twelve variables that could be obtained preoperatively (table 1) and an operative severity score (OSS) that could only be obtained post-operatively containing six variables (table 2).
Logistic regression analysis had shown these 18 variables, selected from an initial group of 62 variables, to be independent prognostic factors for mortality and morbidity in patients who had undergone a variety of elective or emergency general surgical operations. The analysis yielded POSSUM formulas (table 3) that allowed calculation of expected mortality and morbidity for individual patients as well as groups of patients.

The POSSUM system has been validated as a tool to audit the performance of both individual surgeons and surgical departments, especially in colorectal surgery [2-4].
However in 1996 Whiteley *et al.*[5] (the Portsmouth group) evaluated the POSSUM system in patients who underwent operations that were representative of the average operative workload in a general surgical practice. In their series the POSSUM system overpredicted post-operative mortality, and it performed worst in low-risk patients. Using the same variables as were used in the POSSUM system the "Portsmouth" group calculated a new equation to predict mortality. This was the p-POSSUM equation that in 1998, after further studies [6], had evolved to the present formula (table 3). No formula for morbidity was developed by the Portsmouth group.
Wijesinghe *et al.* [7] showed that in vascular surgery the ratio of observed deaths to expected deaths was close to unity if appropriate statistical analyses were used. It transpired that for the p-POSSUM system linear analysis was most appropriate whereas exponential analysis seemed more appropriate for the POSSUM system.

Since then a number of studies have been published on the usefulness of the POSSUM system or the p-POSSUM system in the audit of various types of surgery or even non-surgical procedures [8-39].
It became apparent that in specialised surgery the POSSUM system but also the p-POSSUM system overpredicted mortality especially in low risk groups and at

the extremes of age. This lead to the development of the V-POSSUM (Vascular-POSSUM) equations, the RAAA-POSSUM (Ruptured Abdominal Aortic Aneurysm) equation [40-42], and the O-Possum for oesophago-gastric operations [43].
Subgroup analysis in colorectal surgery showed that the POSSUM system as well as the p-POSSUM system not only overpredicted mortality in young patients and in patients with cancer but also underpredicted mortality in the elderly and in emergency patients [44-49].
This has lead to the development of a dedicated scoring system for colorectal surgery and this is the colorectal POSSUM (cr-POSSUM) [50].
This system uses a selection of the original POSSUM variables (tables 4 and 5). The cr-POSSUM equation is given in table 3. This model was developed in patients who underwent colorectal and anal operations. Some 36% of patients underwent anal procedures and 8% of patients underwent abdominal other than colorectal procedures. It is a matter for debate whether the cr-POSSUM system is representative of the type of colorectal surgery that is dealt with in this thesis that carries a high morbidity rate and a substantial mortality rate.
It has recently been shown in the USA that all three POSSUM variants over predict mortality after colorectal resection [51].
It is however difficult to compare results obtained in the USA to those obtained in Europe. In comparable cohorts of patients a quadruple mortality rate was found in the UK. Unstudied variables may exist between nations. One cannot safely assume that POSSUM based international comparisons are inherently valid [52].

The data in this series were collected retrospectively. The physiological variables were obtained during routine work-up of patients and the operative data were collected from operation notes that are compulsory in The Netherlands. In the present series 95.9% of data were retrieved (95.7% of PS data, 96.3% of OSS data). This is comparable to reported retrieval data of 96% to 99.5% [16,51].
It has been shown that retrospective collection of Possum data is reliable [16]. Missing data have been dealt with in ways ranging from replacement with zero, with a normal value of 1, with an average value per item or even with the first post-operative value. No strategy however affected the accuracy of risk assessment with either POSSUM variant [16,51]. In the present series missing data were replaced by the mean per PS or OSS item.
Using the POSSUM, p-POSSUM and cr-POSSUM equations (table 3) the observed: expected (O:E) death ratios were calculated in our colorectal database. For each patient the expected mortality was calculated and this allowed us to stratify for expected mortality risk. Linear and exponential analysis was also used to calculate observed: expected death ratios in relation to age. The results are

depicted in tables 6-17 and figures 1-4.
In all analyses the POSSUM system overpredicted mortality and this was most severe in low-risk groups.
The p-POSSUM system underpredicted mortality in the linear mortality risk analysis and in the exponential age group analysis.
The p-POSSUM system showed ratios approaching unity in the exponential mortality risk analysis but in the linear age group analysis the p-POSSUM system overpredicted in low-risk patients and underpredicted in high-risk patients.
The cr-POSSUM system underpredicted in all analyses.

In conclusion, the items of the POSSUM scoring system may be used in risk-analysis even if data are retrieved in retrospect. Auditing the performance of individual surgeons or surgical units is possible but expected mortality rates calculated by using the POSSUM, p-POSSUM or cr-POSSUM system can only be used as relative data and one has to use an appropriate analysis of risk stratification.
In the future specialty or regional specific POSSUM based models may be required to evaluate outcome of surgery and there is a need for further validation or recalibration of the POSSUM system.
However until more dedicated systems are developed the POSSUM and p-POSSUM model, with their restrictions, probably represent the benchmark for comparing newer predictive indices and audit systems [53].

TABLE 1 Physiologic Score POSSUM system

Score	1	2	4	8
Age (years)	≤60	61-70	≥71	
Cardiac signs	No failure	Diuretic, digoxin, antianginal or hypertensive therapy	Peripheral edema; warfarin therapy	Raised jugular venous pressure
Chest radiograph			Borderline cardiomegaly	Cardiomegaly
Respiratory signs	No dyspnea	Dyspnea on exertion	Limiting dyspnea (one flight)	Dyspnea at rest (rate ≥ 30/min)
Chest radiograph		Mild COAD	moderate COAD	Fibrosis or consolidation
Blood pressure mm Hg (systolic)	110-130	131-170 100-109	≥171 90-99	≤89
Pulse (beats/min)	50-80	81-100 40-49	101-120	≥121 ≤39
Glasgow coma score	15	12-14	9-11	≤ 8
Hemoglobin (g/100 mL)	13-16	11.5-12.9 16.1-17.0	10.0-11.4 17.1-18.0	≤9.9 ≥ 18.1
White cell count (x10^{12} /L)	4-10	10.1-20.0 3.1-4.0	≥20.1 ≤3.0	
Urea (mmol/L)	≤7.5	7.6-10.0	10.1-15.0	≥15.1
Sodium (mmol/L)	≥136	131-135	126-130	≤125
Potassium (mmol/l)	3.5-5.0	3.2-3.4 5.1-5.3	2.9-3.1 5.4-5.9	≤2.8 ≥6.0
Electro-cardiogram	Normal		Atrial fibrillation (rate 60-90)	Any other abnormal rhythm or ≥5 ectopics/min, Q waves or ST/T wave changes

COAD = chronic obstructive airways disease

Table 2 Operative Severity Score POSSUM system

Score	1	2	4	8
Operative severity*	Minor	Moderate	Major	Major+
Multiple procedures	1		2	>2
Total blood loss (mL)	≤100	101-500	501-999	≥1000
Peritoneal soiling	None	Minor (serous fluid)	Local pus	Free bowel content, pus or blood
Presence of malignancy	None	Primary only	Nodal metastasis	Distant metastasis
Mode of surgery	Elective		Emergent resuscitation of ≥2 h possible. Operation <24 h after admission	Emergent (immediate surgery <2 h needed)

*Surgery of moderate severety includes appendicectomy, cholecystectomy, mastectomy, transurethral resection of prostate; major surgery includes any laparotomy, bowel resection, cholecystectomy with choledochotomy, peripheral vascular procedure or major amputations; major+ surgery includes any aortic procedure, abdominoperineal resection, pancreatic or liver resection, oesophagogastrectomy.

Table 3 Regression Equations in POSSUM, p-POSSUM and cr-POSSUM scoring systems

POSSUM-mortality Ln(P/1-P)= -7.04+(0.13 x PS)+(0.16 xOSS)
POSSUM-morbidity Ln(P/1-P)= -5.91+(0.16 x PS)+(0.19 x OSS)
p-POSSUM-mortality Ln(P/1-P)= -9.065+(0.1692 x PS)+(0.1550 x OSS)
cr-POSSUM-mortality Ln(P/1-P)= -9.167+(0.338 x cr-PS)+(0.308 x cr-OSS)

P= risk of mortality or morbidity;
PS= physiologic score;
OSS= operative severity score

Table 4 Physiologic Score cr-POSSUM system

Score	1	2	3	4	8
Age (years)	≤ 60		61-70	71-80	>80
Cardiac signs	Non or mild	Moderate	Severe		
Blood pressure mm Hg (systolic)	100-170	>170 or 90-99	<90		
Pulse (beats/min)	40-100	101-120	>120 or <40		
Haemoglobine (g/100 mL)	13-16	10-12.9 or 16.1-18	<10 or >18		
Urea (mmol/L)	≤ 10	10.1-15.0	>15		

Table 5 Operative Severity Score cr-POSSUM system

Score	1	2	3	4	8
Operative severity	Minor		Intermediate	Major	Complex major
Peritoneal soiling	None or serous fluid	Local pus	Free pus or feces		
Presence of malignancy	No cancer or Duke's A-B	Duke's C	Duke's D		
Mode of surgery	Elective		Urgent		Emergent

Table 6 Linear analysis of death and Observed: Expected mortality ratios predicted by POSSUM, stratified for POSSUM predicted mortality risk groups

Mortality risk group (%)	no. of patients	Expected mortality	Observed mortality	Observed: expected
<5	456	15	4	0.3
5-<10	370	26	10	0.4
10-<20	347	49	28	0.6
≥20	431	182	104	0.6
total	1604	272	146	0.5

Table 7 Linear analysis of death and Observed: Expected mortality ratios predicted by p-POSSUM, stratified for p-POSSUM predicted mortality risk groups

Mortality risk group(%)	no. of patients	Expected mortality	Observed mortality	Observed: expected
<5	1071	19	29	1.5
5-<10	197	14	19	1.4
10-<20	163	23	28	1.2
≥20	173	74	70	0.9
total	1604	130	146	1.1

Table 8 Linear analysis of death and Observed:
Expected mortality ratios predicted by cr-POSSUM,
stratified for cr-POSSUM predicted mortality risk groups

Mortality risk group(%)	no. of patients	Expected mortality	Observed mortality	Observed: expected
<5	1035	22	33	1.5
5-<10	280	20	31	1.6
10-<20	135	18	22	1.2
≥ 20	154	49	60	1.2
total	1604	109	146	1.3

Fig. 1 Linear analysis of Observed:
Expected mortality ratios predicted by POSSUM, p-POSSUM and cr-POSSUM,
stratified for POSSUM, p-POSSUM and cr-POSSUM predicted mortality risk groups

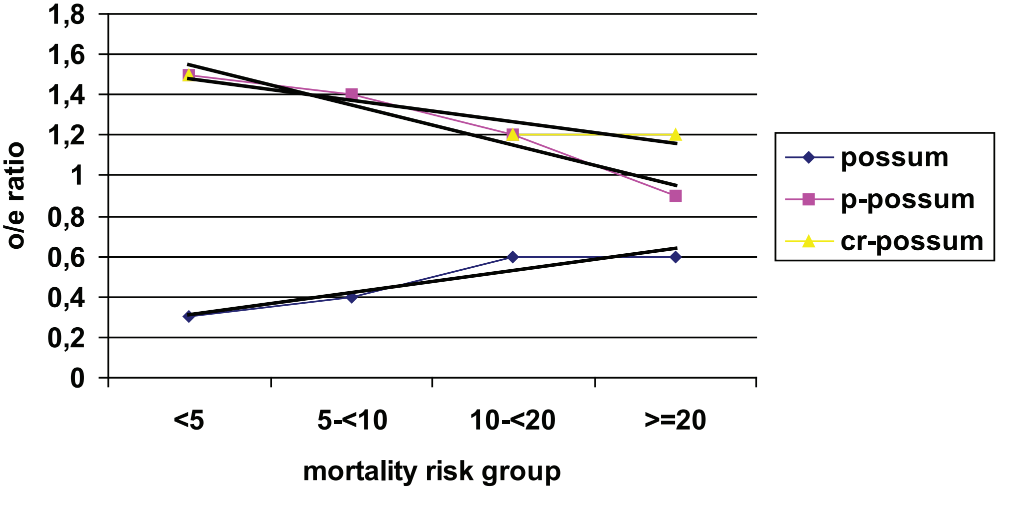


Table 9 Linear analysis of death and Observed:
Expected mortality ratios predicted by POSSUM, stratified for age groups

Age (years) Group	no. of patients	Expected mortality	Observed mortality	Observed: expected
<50	203	17	2	0.1
50-<60	259	25	8	0.3
60-<70	352	51	18	0.4
70-<80	487	99	51	0.5
≥80	303	80	67	0.8
total	1604	272	146	0.5

Table 10 Linear analysis of death and Observed:
Expected mortality ratios predicted by p-POSSUM, stratified for age groups

Age (years) Group	no. of patients	Expected mortality	Observed mortality	Observed: expected
<50	203	5	2	0.4
50-<60	259	9	8	0.9
60-<70	352	21	18	0.9
70-<80	487	50	51	1.0
≥80	303	46	67	1.5
total	1604	131	146	1.1

Table 11 Linear analysis of death and Observed:
Expected mortality ratios predicted by cr-POSSUM, stratified for age groups

Age (years) Group	no. of patients	Expected mortality	Observed mortality	Observed: expected
<50	203	3	2	0.7
50-<60	259	4	8	2.0
60-<70	352	13	18	1.4
70-<80	487	27	51	1.9
≥80	303	62	67	1.1
total	1604	109	46	1.3

Fig. 2 Linear analysis of Observed:
Expected mortality ratios predicted by POSSUM, p-POSSUM and cr-POSSUM, stratified for age groups

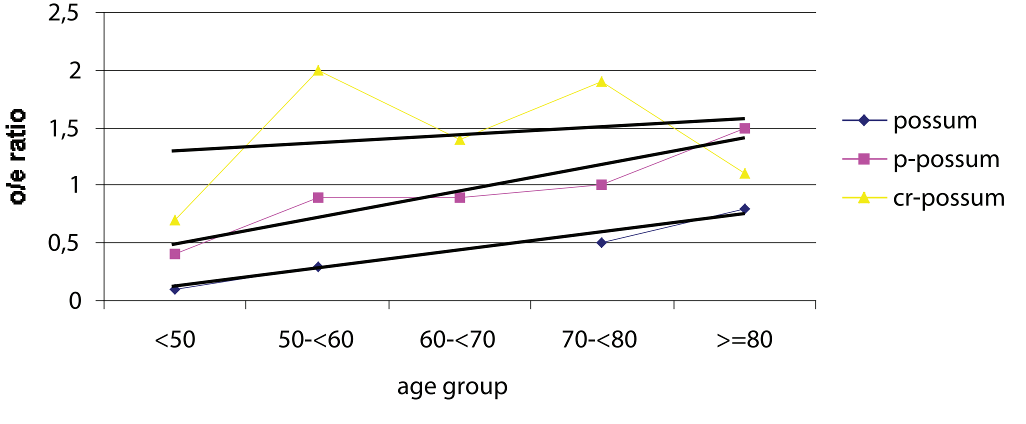


Table 12 Exponential analysis of death and Observed: Expected mortality ratios predicted by POSSUM, stratified for POSSUM predicted mortality risk groups

Mortality risk group (%)	no. of patients	Expected mortality	Observed mortality	observed: expected
0-100	1604	272	146	0.5
5-100	1148	257	142	0.6
10-100	778	231	132	0.6
15-100	574	207	120	0.6
20-100	431	182	104	0.6
25-100	344	163	98	0.6
30-100	278	145	87	0.6
35-100	231	129	80	0.6
40-100	179	110	72	0.7
45-100	158	101	66	0.7
50-100	129	87	58	0.7
55-100	105	74	48	0.6
60-100	83	62	42	0.7
65-100	64	50	37	0.7
70-100	50	40	32	0.8
75-100	37	31	28	0.9
80-100	26	23	21	0.9
85-100	15	14	15	1.1
90-100	6	6	6	1.0
95-100	2	2	2	1.0

Table 13 Exponential analysis of death and Observed: Expected mortality ratios predicted by p-POSSUM, stratified for p-POSSUM predicted mortality risk groups

Mortality risk group (%)	no. of patients	Expected mortality	Observed mortality	Observed: expected
0-100	1604	130	146	1.1
5-100	533	110	117	1.1
10-100	336	97	98	1.0
15-100	241	85	80	0.9
20-100	173	74	70	0.9
25-100	138	66	63	1.0
30-100	109	58	52	0.9
35-100	96	54	48	0.9
40-100	76	46	42	0.9
45-100	62	40	36	0.9
50-100	51	35	34	1.0
55-100	38	28	27	1.0
60-100	33	25	24	1.0
65-100	28	22	20	0.9
70-100	22	18	18	1.0
75-100	18	15	17	1.1
80-100	13	11	13	1.2
85-100	9	8	9	1.1
90-100	4	4	4	1.0
95-100	1	1	1	1.0

Table 14 Exponential analysis of death and Observed: Expected mortality ratios predicted by cr-POSSUM, stratified for cr-POSSUM predicted mortality risk groups

Mortality risk group (%)	no. of patients	Expected mortality	Observed mortality	Observed: expected
0-100	1604	109	146	1.3
5-100	568	87	113	1.3
10-100	289	67	82	1.2
15-100	206	57	71	1.2
20-100	154	49	60	1.2
25-100	109	39	46	1.2
30-100	64	27	33	1.2
35-100	34	17	23	1.4
40-100	32	16	22	1.4
45-100	22	12	18	1.5
50-100	11	7	11	1.6
55-100	10	6	10	1.7
60-100	7	5	7	1.4
65-100	4	3	4	1.3
70-100	1	1	1	1.0
75-100	0	0	0	
85-100				
90-100				

Fig. 3 Exponential analysis of Observed:
Expected mortality ratios predicted by POSSUM, p-POSSUM and cr-POSSUM, stratified for POSSUM, p-POSSUM and cr-POSSUM predicted mortality risk groups

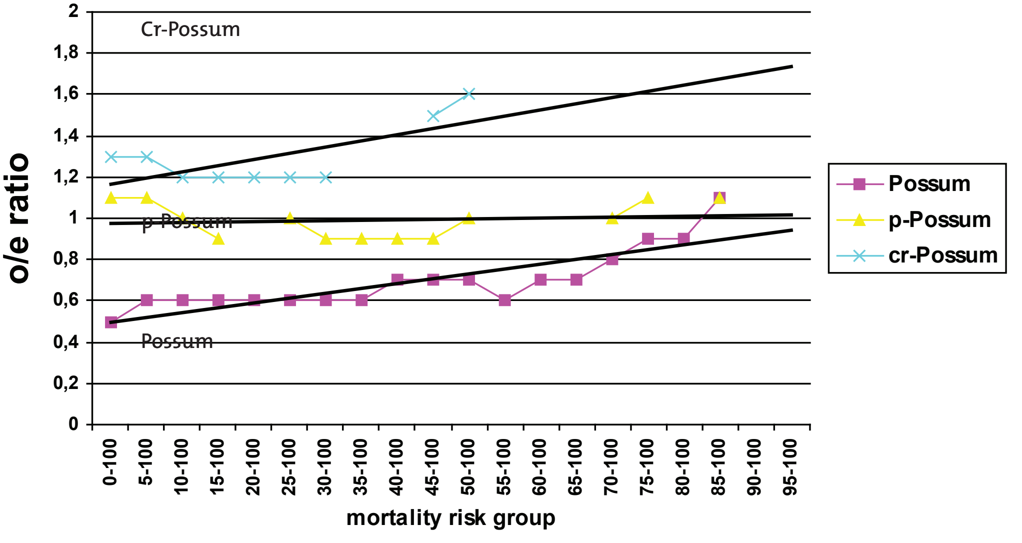


Table 15 Exponential analysis of death and Observed:
Expected mortality ratios predicted by POSSUM, stratified for age groups

Age Group (%)	no. of patients	Expected mortality	Observed mortality	Observed: expected
0-100	1604	272	146	0.5
50-100	1401	255	144	0.6
60-100	1142	230	136	0.6
70-100	790	179	118	0.7
80-100	303	80	67	0.8
90-100	30	10	8	0.8

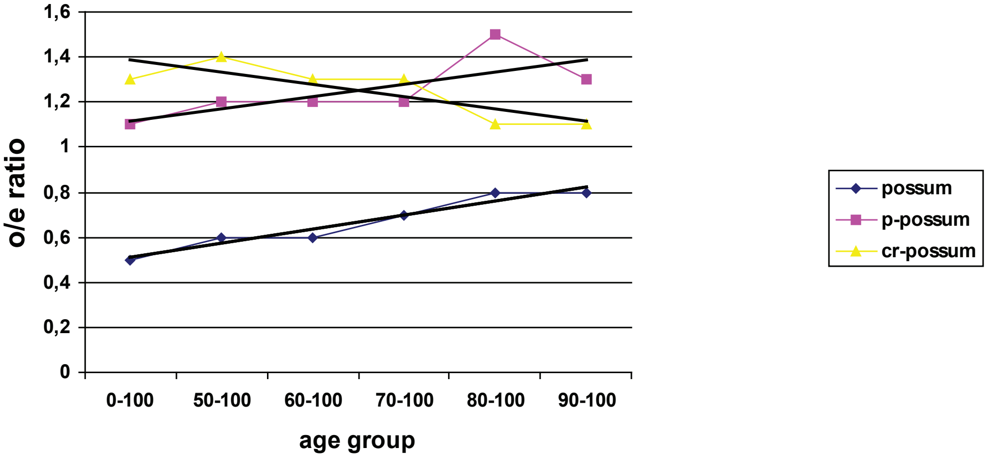
Table 16 Exponential analysis of death and Observed:
Expected mortality ratios predicted by p-POSSUM, stratified for age groups

Age Group (%)	no. of patients	Expected mortality	Observed mortality	Observed: expected
0-100	1604	130	146	1.1
50-100	1401	125	144	1.2
60-100	1142	116	136	1.2
70-100	790	95	118	1.2
80-100	303	46	67	1.5
90-100	30	6	8	1.3

Table 17 Exponential analysis of death and Observed:
Expected mortality ratios predicted by cr-POSSUM, stratified for age groups

Age Group (%)	no. of patients	Expected mortality	Observed mortality	Observed: expected
0-100	1604	109	146	1.3
50-100	1401	106	144	1.4
60-100	1142	102	136	1.3
70-100	790	94	118	1.3
80-100	303	62	67	1.1
90-100	30	7	8	1.1

Fig. 4 Exponential analysis of Observed:
Expected mortality ratios predicted by POSSUM, p-POSSUM and cr-POSSUM, stratified for age group



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1.4 Outline of the thesis

The ultimate result of a surgical procedure depends on several factors. The patient's physiologic status, the disease that requires surgery, the decision to operate, the nature of the operation, the technical skills of the surgeon, and the support services before and after the operation all have an effect, some to a lesser degree, on the ultimate outcome.
This thesis investigates and tries to clarify some aspects in the ultimate outcome of colorectal surgery.

In chapter 1, some factors or combination of factors important in the outcome of surgical care are discussed. The underlying database of the studies in this thesis is presented and the risk-analysis system is described. The predicted mortality of the whole patient group is calculated with the POSSUM, p-POSSUM and cr-POSSUM equilibrations and compared with the observed mortality in linear and exponential analyses in several mortality and age groups.
Chapter 2 describes the outcome of elective primary surgery in a well-described group of patients with nonacute complications of diverticular disease of the sigmoid colon. Risk-analysis is based on the POSSUM scoring system
The risk factors related to mortality after surgery for acute complications of diverticular disease of the sigmoid colon are addressed in chapter 3.
The decision about which surgical procedure will be performed for complicated diverticular disease must be evidence based.
In chapter 4, we describe the outcome of all patients who survived after a primary acute or elective Hartmann procedure for complicated diverticulitis.
In chapter 5, we compared the outcome of elective surgery of the sigmoid colon for complicated diverticulitis or carcinoma done by the same group of surgeons in the same period. We also investigated whether recalibration of the original POSSUM equilibration is necessary in this subgroup analysis.
Training and specialization lead to better results in colorectal surgery. The aim of the Dutch national TME trial was to reduce the numbers of local recurrence by having well-trained and specialized surgeons operate on all patients. We wondered if this nationwide training and specialization, as a side effect, changed the surgical practice regarding the use of abdominoperineal resection and low anterior resection in The Netherlands and whether changes in surgical practice affects post-operative hospital mortality for abdominoperineal resection and low anterior resection. These questions are answered and discussed in chapter 6.

The volume-outcome discussion is, with the exception of the TME trial, not an item in the field of colorectal surgery in The Netherlands. Nevertheless, in chapter 7 we analyzed the hospital variation in post-operative mortality after colorectal resections in The Netherlands.

Chapter 2

OUTCOME OF ELECTIVE PRIMARY SURGERY FOR DIVERTICULAR DISEASE OF THE SIGMOID COLON: A RISK ANALYSIS BASED ON THE POSSUM SCORING SYSTEM

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ABSTRACT

Background:

The outcome of surgery for diverticular disease of the sigmoid colon remains largely unclear. A comparison of studies is hardly possible because risk factors for diverticular disease severity and patient-related risk factors are lacking. The purpose of this study was to define morbidity and mortality of primary surgery for non-acute complications of diverticular disease of the sigmoid colon and to identify the risk factors that predict a higher morbidity and mortality.

Methods:

Patients who underwent elective surgery for complications of diverticular disease of the sigmoid colon (n = 149) were identified in a prospective computerized morbidity and mortality registration. In all patients, the Physiologic and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) was calculated, as were the morbidity and mortality rates. Factors predicting post-operative morbidity and mortality were identified. To audit mortality figures, a POSSUM based scoring system is introduced.

Results:

The mortality rate was 4.7% and morbidity rate was 53.7%. Significantly higher morbidity rates were correlated with a higher physiologic POSSUM score (P=0.010). Non-survivors were older (P=0.029) and also had a higher physiologic POSSUM score (P<0.001) and operation severity POSSUM score (P<0.001)

Conclusion:

The morbidity and mortality rates of surgery for non-acute complications of diverticular disease of the sigmoid colon are considerable. To a large extent, mortality and morbidity are driven by patient- and disease-related factors, as expressed by elevated physiologic severity and operative severity scores and failures of perioperative management in most deceased patients.

Introduction

Diverticulosis of the colon, especially in the sigmoid, is a common benign condition that is increasing in the Western population. It is estimated to occur from less than 10% in those younger than 40 years old to an estimated 50% to 66% of patients over age 80 [1-3].
The increasing average age and the changing diet in this group will raise the incidence of diverticulitis of the sigmoid and its complications. It is not possible to predict the likelihood of serious complications, but 10% to 25% of patients with diverticulitis will have complications, from which about 35% will ultimately need an operation [4-14].

Although the surgical procedure of choice is open to debate, the indications of surgery when acute complications occur are clear, especially in cases of perforation and colonic obstruction. Less well defined are the indications for elective surgery after the successful conservative treatment of diverticulitis of the sigmoid or for uncomplicated diverticulosis with functional complaints. The literature is divers and published series are not always comparable.
In the absence of prospective randomized trials, detailed figures in well-described patient populations are necessary to make an evidence-based decision to operate or to make a medical audit possible.
Our study describes the results of surgical treatment of 149 patients who underwent elective surgery for diverticular disease of the sigmoid over a consecutive 12-year period and identifies the factors leading to complications and mortality.

Patients and methods

Database

From 1990 to 2002, a prospective computerized morbidity and mortality registration was carried out for all patients admitted to the surgical wards by one of the authors (JLTO). Patients who underwent planned elective surgery for diverticular disease of the sigmoid were identified. Diagnosis of diverticulitis was confirmed by pathologic examination.

Type of surgery

The types of surgery used were as follows:
Sigmoid resection: resection and anastomosis.
Hartmann procedure: resection of diseased sigmoid, closure of distal part, and

end colostomy of the proximal colon.
Primary surgery: first operation, nonurgent and routinely planned for diverticular disease of the sigmoid colon.
Re-operation: any re-operation during the original hospital admission.

Risk stratification of patients

The Physiologic and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) scoring system was used to identify patient-related risk factors to provide an objective measure to assess morbidity and mortality data. The data necessary to calculate the POSSUM score were retrospectively collected by one of the authors (JLTO), who found 96.1% of the data (physiologic score [PS], 94.9%; operative severity score, [OSS] 98.5%). The PS and OSS were calculated for each patient.
The POSSUM formula was used to calculate the expected mortality for each patient, which allowed us to stratify groups. Four bands of increasing POSSUM-predicted mortality were examined 0% to <5% (group I), 5% to <10% (group II), 10% to <20 % (group III) and ≥20% (group IV). Predicted mortality was compared with the observed death in each group. This provided a scoring system that was also meaningful in the clinical setting.

Hinchey classification

The Hinchey classification was used to score the severity of the diverticulitis:
Stage I: Contained pericolic abscess or phlegmonous diverticulitis.
Stage II: Walled-off pelvic abscess.
Stage III: Generalized purulent peritonitis, no free communication with the lumen of the colon.
Stage IV: Faecal peritonitis, free communication with the lumen of the colon.

Complications

Complications that were registered prospectively are listed in Table 1.

Perioperative management failure

Although a retrospective analysis of complex treatment is difficult, an effort was made to evaluate the surgical management of these patients. Group 1: no management failure, death was related to patient factors. Group 2: possible management failure despite severe patient-related factors. Group 3: definite management failure. Group 4: no evaluation possible

Statistical analysis

Data were analysed using Statistical Package for the Social Sciences (SPSS) software (verse 9.0) (SPSS Inc., Chicago, IL, USA). The Pearson chi-square test, the Fisher exact test and the Student *t*-test for equality of means were used when appropriate. Significance was evaluated at *P*= 0.05.

Results

A total of 149 patients, mean age 64 years (range: 31 to 89; std deviation: 11.0), underwent surgery for diverticular disease of the sigmoid colon. There were 98 (66%) women and 51 (34%) men, and the men (average age of 61 years) were significantly younger than the women (average age of 66 years) (*P*= 0.008).

Indications

The indications of elective surgery were fistulae (n =28): colovesical fistulae (n = 25); coloenterovesical fistula (n =1); colovaginal fistulae (n = 2). Recurrent attacks of diverticulitis without septic complications (n = 59). Diverticulitis with septic complications (n = 6); comprising liver abscess in 2, colisepsis in 1 and pelvic abscess in 3. Functional complaints (n =22), bleeding (n =2) or stenosis with or without suspicion of malignancy (n = 32) (Table 2).

Men (16 /51) had more fistulae then women (12 /96) (*P*= 0.005).

At operation, a pelvic rest abscess was found in 2 patients and chronic diverticulitis without abscesses in 11, which means that 147 patients had Hinchey stage I disease and in 2 patients Hinchey stage II diverticular disease was present.

Type of primary surgery

Sigmoid resection was performed in 139 patients (6 with covering stoma) and 10 patients had a Hartmann procedure. No differences between gender and type of surgery were found (*P*=0.736); however, more Hartmann procedures were performed (*P*= 0.021) in the patients with fistulae. In 33 patients (22%), more than one procedure was done. The type and frequency of the multiple procedures are given in Table 3.

Re-operations

Eighteen patients (12%) had 28 re-operations: 13 patients had 1 re-operation, 3 patients had 2, 1 patient had 3, and 1 patient had 6 re-operations. Re-operations were performed for anastomotic leak in 9, re-bleeding in 4 and ongoing abdominal sepsis in 2. Re-operations performed were 8 Hartmann procedures, 2 loop colostomies, 14 exploratory laparotomies and 1 each splenectomy, tracheotomy, abscess drainage and ileocoecal resection.

POSSUM scoring

The average POSSUM score was 29 (range, 21-62). The PS average was 17 (range, 12-43) and the OSS average was 12 (range, 9-23). The POSSUM predicted mortality was 7.7% (range, 1.7%-3.1%), with a predicted morbidity of 30.5% (range, 9.3% - 9.0%).

Morbidity

Patients whose general condition demanded intensive treatment and patients with significant post-operative complications were cared for in a dedicated intensive care setting that did not change during the study period. At least 1 complication developed in 80 patients (53.7%), and 2 or more complications developed in 28 patients (18.8%). After exclusion of urinary tract infections related to indwelling urinary catheters, morbidity was still seen in 30.2% of patients.

Patients with complications had a higher PS (P= 0.010) compared with patients with no complications. The items in the POSSUM scoring system that led to this higher PS were changes in blood pressure, pulse rate, and haemoglobine levels. Women had more complications (P= 0.004) because of higher percentages of urinary tract infections. Men had more intra-abdominal abscesses (P= 0.018) and underwent more re-operations for complications (P= 0.042).

Ten anastomotic leaks were seen after sigmoid resection in 139 patients. Of these 10 patients, 1 was treated conservatively and 9 patients were re-operated (Hartmann procedure), but 2 died from ongoing sepsis. Table 4 lists the type and frequency of post-operative complications in our series.

Mortality

Seven of 149 patients died in the hospital (mortality rate: 4.7 %.). Thirty-day mortality was 3.4%. Non-survivors were older (73 v. 64 years, P= 0.029) and had a higher PS (P< 0.001) and OSS (P< 0.001). The items from the POSSUM scoring system leading to higher PS were age and changes in pulse rate, haemoglobine, white cell count and urea, sodium and potassium. Factors for a higher OSS were multiple surgical procedures and amount of blood loss during the primary operation.

Non-survivors (n = 7) had more re-operations (P< 0.001), more complications (P= 0.015) and suffered more multiple complications (P< 0.001) than the survivors (n = 142).

No differences were found in mortality between the resection and anastomosis group or Hartmann group (P=0.392) or between gender (P=0.231).

Table 5 shows the relation between the operation indications, type of operation, gender and mortality. Type and frequency of post-operative complications in relation with mortality are given in Table 6.

POSSUM based stratification and mortality

For each non-survivor, a POSSUM-predicted mortality was calculated and patients were allocated to1of 4 POSSUM risk groups (see methods). For each POSSUM risk group, predicted and observed number of deaths was calculated (Table 7). Details and co-morbidity of all deceased patients are listed in Table 8.

Perioperative management failure and mortality

Group 1, no management failure (n = 3).
Group 2, possible management failure (n = 3). In the first patient, who was treated for pulmonary embolus, the diagnosis of an anastomotic leak was significantly delayed. In the second, post-operative bleeding occurred. The third patient underwent a negative laparotomy for ongoing sepsis caused by unrecognized pyelonephritis with abscesses revealed by autopsy.
Group 3, definite management failure, included no patients.
Group 4, 1 patient for which too little clinical information was present to allow evaluation of perioperative management.

Discussion

The 4.7% overall mortality and 53.7% morbidity after elective operation in the series presented here may seem high compared with the 0% to 2.2% mortality rates published in the literature [15-27]. These differences could be related to different patient populations or a different indication policy for surgery, such as a more aggressive indication for resection after a first attack of diverticulitis.
The strict indication for elective resection in the series according to the guidelines of the American College of Gastroenterology and The American Society of Colon and Rectal Surgeons [28,29] may only partly explain the difference in the mortality found between our series and those published in the literature. But to properly audit the mortality and morbidity after a determined surgical procedure, variations in surgical performance between hospitals and individual surgeons have to be compared by the POSSUM scoring system.
POSSUM was developed in 1991 by G.P. Copeland *et al.* [30] as a method to compare and predict mortality and morbidity through a risk-adjusted analysis between patient populations with different case mix and fitness. It uses a 12-factor, 4-grade physiologic score and a 6-factor, 4-grade operative severity score.
The POSSUM score is used for different diseases and patient processes, but for the stratification of results of colorectal surgery, the available literature is scarce [31-34]. Applying the POSSUM scoring system and equation method to the 149 patients in this series, who underwent an elective sigmoid resection for diverticular disease, resulted in an overall predicted mortality of 7.8%, whereas the actual rate was 4.7%. Moreover, in the 4 groups of patients with an increasing

POSSUM score (<5, 5 to <10, 10 to <20, and ≥ 20), the predicted and obtained mortality were concordant, especially for groups III and IV (13.3% *vs.* 14% and 40.1% *vs.* 33%), however the obtained the obtained mortality in groups I and II was remarkably lower than predicted (3.1% *vs.*1% and 7.2 *vs.* 2%). These results stress the consideration that in our series, morbidity and mortality were only predicted by patient- and disease-related factors and not by hospital- or surgeon-related factors. The performed analysis of the perioperative management confirmed this conclusion. Moreover to reduce mortality, we have to consider the indication for operation very carefully and find out how to distinguish patients who need an operation from those in whom conservative treatment should be chosen. The presentation of the analyses of the results here obtained can help to achieve a better understanding of the multiple factors that can lead to different results. Indication for surgery, the surgeon as a factor of success or failure and the patient with his or her mortality has to be taken as a whole in account, as the POSSUM score does, to compare the results of international series.

Table 1 Registered complications

Type of registered complications
1. Deep wound infection: lay open of the wound was mandatory 2. Intra-abdominal abscess: confirmed by laparotomy or percutaneous drainage 3. Anastomotic leak: confirmed by intraluminal contrast studies and/or laparotomy 4. Re-bleeding or significant wound haematoma 5. Pulmonary: confirmed by chest X-ray and/or mucus cultures 6. Thrombosis and/or pulmonary emboli: confirmed by either venography, duplex sonography and ventilation/perfusion scans 7. Pressure ulcers 8. Urinary tract: infections confirmed by urine cultures 9 Cardiac: confirmed by electrocardiography and or CK/CKMB studies or by X ray thorax 10. Central nervous system: confirmed by computed tomography scan 11. Sepsis: confirmed by blood cultures 12. Miscellaneous 13. Multiple organ failure

Table 2 Operation indications

Operation indication	No. of patients
Fistula	
colovesical	25
coloenterovesical	1
colovaginal	2
Septic complications	
liver abcess	2
pelvic abcess	3
colisepsis	1
recurrent diverticulitis	59
Stenosis	32
Functional complaints	22
Bleeding	2
Total	149

Table 3 Type and frequency of the multiple procedures

Type concomitant operation in 39 patients	No. of patients
Splenectomy	1
Resection small intestine	4
Stoma formation	6
Cholecystectomy	1
Partial cystectomy	16
Adnex extirpation	4
Uterus extirpation	1
Total	33

Table 4 Complications

Type complication	Men %	Women %	Total %	*P* value
01: wound infection	12%	15%	14%	n.s.
02: intraabominal abscess	10%	1%	4%	0.018
03: anastomotic leak	10%	5%	7%	n.s.
04: rebleeding/haematoma	8%	2%	4%	n.s.
05: airways	14%	7%	9%	n.s
06: thrombo/emboly	6%	3%	4%	n.s.
07: pressure ulcers	2%	1%	1%	n.s.
08: urinary tract	22%	46%	38%	0.004
09: cardiac	6%	6%	6%	n.s.
10: CNS	0%	0%	0%	
11: sepsis	8%	4%	5%	n.s.
12: miscelleneous	12%	11%	11%	n.s.
13: MOF	2%	1%	1%	n.s.

CNS = central nervous system; MOF = multiple organ failure; n.s.=not significant

Table 5 Operation indication, type of operation and mortality

Operation Indication	Type of operation	men	women	total	Mortality men	Mortality women	Mortality total
Fistula (n = 28)	Resection with anastomosis	14	9	23	1	1	2
	Hartmann	2	3	5	1		1
Other indications (n = 121)	Resection with anastomosis	33	83	116	2	2	4
	Hartmann	2	3	5			
Total (n = 149)		51	98	149	4	3	7

Table 6 Type and frequency of complications between non-survivors and survivors

Type complication	Non-survivors %	Survivors %	Total %	*P* value
01: wound infection	14%	14%	14%	n.s.
02: intra-abdominal abscess	28%	3%	4%	0.026
03: anastomotic leak	28%*	6%*	7%*	0.011
04: rebleeding/hematoma	14%	3%	4%	n.s.
05: airways	57%	7%	9%	0.001
06: thrombo/emboly	29%	3%	4%	0.026
07: pressure ulcers	0%	1%	1%	n.s.
08: urinary tract	43%	37%	38%	n.s.
09: cardiac	43%	5%	6%	0.005
10: CNS	0%	0%	0%	
11: sepsis	86%	1%	5%	<0.001
12: miscellaneous	29%	7%	8%	<0.001
13: MOF.	29%	0%	1%	n.s.

CNS = central nervous system; MOF = multiple organ failure; n.s.=not significant
* Calculated for the resection with anastomosis group

Table 7 Predicted and observed number of deaths

POSSUM risk group	No. of patients	Mean predicted POSSUM mortality No. of patients	Observed mortality No. of patients
Group I (<5)	87	3	1
Group II (5 to <10)	43	3	1
Group III (10 to <20)	7	1	1
Group IV ($\geq$ 20)	12	5	4
Total	149	12	7

Table 8 Details and co-morbidity of all deceased patients

Gender	Age (years)	POSSUM predicted mortality (%)	POSSUM group	Operation indication	Type of complications (numbers refer to Table 1)	Co-morbidity
f	55	9%	II	Suspect carcinoma	5,11,12	Severe rheumatoid arthritis, corticosteroids
m	74	34%	IV	Suspect carcinoma	1,5,6,8, 9,11,12	End stage COPD, parox. atrial flutter.
f	87	11%	III	Rec. Ileus	9,11,12	Rheumatoid arthritis
m	72	41%	IV	Suspect carcinoma	4	Hypertension
f	82	22%	III	Colovesical and entero-entero fistula	3,5,11	None
m	65	4%	I	Colovesical fistula	3,6,8, 9,11,13	Hypertension, DVT, and lung emboli
m	77	83%	IV	Colovesical fistula	2,5,8,11,13	Hypertension, aortic valve insufficiency, diffuse arteriosclerotic vascular diseases

COPD, chronic obstructive pulmonary disease ; DVT, deep vein thrombosis

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Chapter 3

MORTALITY AFTER ACUTE SURGERY FOR COMPLICATIONS OF DIVERTICULAR DISEASE OF THE SIGMOID COLON IS ALMOST EXCLUSIVELY RELATED TO PATIENT RELATED FACTORS

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ABSTRACT

Background:

auditing the outcome of surgery for complicated diverticulitis of the sigmoid colon is difficult A comparison of studies is hardly possible because risk factors both in term of the severity of diverticulitis and patient-related risk factors are neither well described nor standardized. The purpose of this study was to define morbidity and mortality of primary surgery for acute complications of diverticular disease of the sigmoid colon and to identify the relation between risk factors and morbidity and mortality.

Methods:

In a prospective computerised morbidity and mortality registration from 1990 to 2002, 114 patients, who underwent surgery on an acute or urgent base for acute complications of diverticular disease of the sigmoid colon, were identified. In all patients the POSSUM score was calculated. To audit mortality rates a POSSUM based scoring system was introduced.

Results:

Mortality rates were 16.7%, morbidity 71.1%. Higher morbidity rates were significantly related to a higher POSSUM Physiological Score (P=0.012) and to older age (P<0.001). Higher mortality rates also were significantly related to a higher POSSUM Physiological Score (P<0.001) and older age (P=0.003). Patients who died had significantly more sepsis (P<0.001), multiple organ failure (P=0.027), cardiac (P<0.001) and pulmonary (P=0.013) complications. Gender, operation indication and type of neither surgery nor surgeon had a significant relation with morbidity or mortality.

Conclusion:

Surgery for acute complications of diverticular disease of the sigmoid colon carries a high morbidity rate and a substantial mortality rate. The majority of deceased patients had severe comorbidity. Post-operative mortality and morbidity are to a large extent driven by patient related factors. Elevated physiological severity scores and a lack of peri-operative management failures express this in the majority of deceased patients.

INTRODUCTION

The incidence of diverticulosis is rising. It is less than 10% in those under 40 years of age but may be as high as 66% in octogenarians [1,2]. Both increasing age and a diet low in fibre are independent risk factors for the development of diverticulosis [3]. Whether or not serious complications of diverticulosis will develop is impossible to predict in the individual, but 10-25% of patients with diverticulosis will develop diverticulitis and one in three of these patients will ultimately need surgery. Clinical treatment for acute complicated diverticulitis will fail in 24-29% of patients leading to acute or subacute surgery during the hospital admission [4-9]. If type of surgery is still a matter for debate the indications for acute surgery i.e. generalized peritonitis, perforation, bleeding and colonic obstruction are not.

Auditing the outcome of surgery for complicated diverticulitis is difficult because a comparison of available data is not possible. This is due to the fact that the various risk factors have not been defined in a standardized way and therefore an interstudy comparison of the interplay between these risk factors and outcome of surgery is unreliable.

The aims of this study were to define morbidity and mortality of primary surgery for acute complications of diverticulitis of the sigmoid colon and to asses the association between these risk factors with morbidity and mortality, in a group of patients rigorously defined for severity of diverticulitis and patient risk factors.

PATIENTS AND METHODS

DATABASE

From 1990 to 2002 a prospective computerized morbidity and mortality registration was carried out for all patients admitted to the surgical wards by one of the authors (JLTO). Patients who underwent surgery on an acute or urgent base for acute complications of diverticulitis of the sigmoid colon were identified. A total of 114 patients of mean age 67 years (range 29-89) suffered acute complications of diverticulitis of the sigmoid colon and underwent surgery for the following indications: perforation/peritonitis (62 patients), colonic obstruction (24 patients) and failed conservative treatment (28 patients). Surgery being mandatory as dictated by the course of the disease. Ten general surgeons operated all the patients. Sigmoid resection and primary anastomosis was never performed in Hinchey III and IV stages.

TYPE OF SURGERY

The types of surgery were defined as follows;

SIGMOID RESECTION: RESECTION AND ANASTOMOSIS

Hartmann's procedure: resection of diseased sigmoid, closure of distal part and end colostomy proximal colon.
Laparotomy and colostomy: laparotomy, no resection, loop colostomy.
Primary surgery: first operation for complications of acute diverticulitis.
Re-operation: any re-operation during the original hospital admission.
Secondary surgery: any operation after discharge.

HINCHEY CLASSIFICATION

The Hinchey classification [10] was used to score the severity of the diverticulitis as follows:
Stage I: Contained pericolic abscess or phlegmonous diverticulitis.
Stage II: Walled-off pelvic abscess.
Stage III: Generalized purulent peritonitis, no free communication with the lumen of the colon.
Stage IV: Faecal peritonitis, free communication with the lumen of the colon.

RISK STRATIFICATION OF PATIENTS

The POSSUM scoring system [11] was used to identify patient related risk factors to provide an objective measure to assess morbidity and mortality data. The data necessary to calculate the POSSUM score were retrospectively collected by one of the authors (JLTO), 95.1% of the data could be found. Missing values were replaced with the average ones per score. Physiological score (PS) and operative severity score (OSS) were calculated for each patient. Expected mortality for each patient was calculated using the POSSUM formula.
To audit mortality we applied the linear regression method as used by Whiteley *et al.* [12],
Prytherch *et al.* [13] and recently by Bennett-Gerrero *et al.* [14], Lam *et al.* [15] and Mohil *et al.* [16].

COMPLICATIONS

Type and definition of prospectively registered complications are listed in Table 1.

PERI-OPERATIVE MANAGEMENT FAILURE

Patients who died were placed in four groups as follows:
Group 1: no management failure, death related to patients factors.

Group 2: possible management or technical failure.
Group 3: definite management failure.
Group 4: no evaluation possible.

STATISTICAL ANALYSIS

Data were analysed using Statistical Package for the Social Sciences (SPSS) software (verse 9.0) (SPSS Inc., Chicago, IL, USA). The Pearson chi-square test, Fisher's exact test and Student t-test for equality of means were used when appropriate. Significance was evaluated at the 0.05 level.

RESULTS

GENDER

There were 67 (59%) women and 47 (41%) men. The men were significantly younger than women (P= 0.007)
No differences were found between gender and any of the following: indication for surgery (P=0.192), type of surgery (P=0.122), operation indication (P=0.192), morbidity (P=0.154), mortality (P=0.349), re-operations (P=0.410), POSSUM scoring (PS: P=0.762, OSS: P=0.068) or Hinchey classification (Hinchey I-II or Hinchey III-IV: P= 0.074).

TYPE OF SURGERY

The type of surgery, indication for surgery, and Hinchey classification, are listed in Table 2.
There were 81 Hartmann procedures (71.1%), 21 resections and primary anastomosis (18.4%) and 12 (10.5%) loop colostomies.
Patients having a sigmoid resection (n =102) had a higher Hinchey stage (P=0.014).
No differences could been found between type of surgery and gender (P=0.758), morbidity (P=0.504), mortality (P=0.687) or POSSUM scoring (PS: P=0.477, OSS: P=0.308).

HINCHEY CLASSIFICATION

Sixty-seven patients were Hinchey I or II and 47 patients were Hinchey III or IV.
Patients with Hinchey classification III-IV had higher POSSUM scores (PS: P=0.022, OSS: P<0.001).There was no difference between Hinchey classification I/II and III/IV and morbidity (P=0.800), mortality (P=0.269) or gender (P=0.074).

POSSUM SCORE

Mean Possum score was 41.5 (range 24-70). Mean PS was 24 (range 12-48) and mean OSS was 17.8 (range 9-33.3). The mean Possum-predicted mortality was 30.4% (range 1.7%-98.9%)

MORBIDITY

At least one complication developed in 81 patients (71.1%) and 46 patients (40.4%) developed two or more. Patients who developed complications were older (mean age 70 *vs.* 58 yr, *P*<0.001, 95% ci: 6.9 to 0.05), needed more re-operations (*P*=0.001, ^{2} :18 /81 *vs.* 0/33,) and had a higher PS (mean 25 *vs.* 21, *P*=0.012, 95% ci: 0.891- 6.998) than those who did not. Five anastomotic leaks occurred in 21 patients having primary anastomosis. Of these three survived and two died from ongoing sepsis.

Post-operative complications are shown in Table 3.

Eighteen (15.8%) patients had 35 re-operations: including one in 9 patients, two in 4 patients, three in 2 patients, and four in 3 patients. The most frequent indication for re-operation was abdominal sepsis (n =22) (Table 4).

MORTALITY

Nineteen patients died giving an in-hospital mortality rate of 16.7 %. The 30-day mortality rate was 14.9%. There were no differences in gender (*P*=0.349), indication for surgery (*P*=0.808) or type of surgery (*P*=0.687) between survivors and non-survivors. There was no significant relationship between mortality and surgeon (*P*=0.816) or Hinchey classification (*P*=0.269). Mortality rate in patients needing a re-operation was 26% (*P*=0.168).

Non-survivors were older (*P*=0.003, mean age 75 *vs.* 65 yr., 95% ci: 3.452 to 16.471), had a higher morbidity (*P*=0.001, ^{2}: 19/19 *vs.* 62/95,) and suffered more than one complication (*P*=0.017, ^{2}: 13/19 *vs.* 33/95,). Non-survivors had a higher PS (*P*<0.001, mean PS: 30 *vs.* 23, 95% ci: 3.4-10.6) and more pulmonary (*P*=0.013, ^{2} : 11/19 *vs.* 27/95) and cardiac (*P*<0.001, ^{2} :7/19 *vs.* 7/95) complications, more sepsis (*P*<0.001, Fishers exact 8/19 *vs.* 3/95) and more multiple organ failure (*P*=0.027 Fishers exact 2/19 *vs.* 0/95) (Table 5).

SECONDARY SURGERY

Eighty-nine secondary operations including 80 colonic procedures and 9 incisional hernia repairs were performed. Of the 81 patients who had a Hartmann's procedure 67 (82.7%) patients survived but a further 5 patients died within three months after discharge from hospital. Reversal of the Hartmann's procedure as a secondary procedure was undertaken in 57 (91.9%) of 62 surviving patients. This was successful in 56 patients and two patients died from post-operative complications.

Ultimately, only 8 patients of the surviving 88 patients had a permanent colostomy.

Risk stratification

Four groups of POSSUM predicted mortality were identified including 0-<5 percent, 5-<10 percent, 10-<20 percent and >= 20 percent. Predicted mortality was compared with the observed death in each group (Table 6).

Perioperative management failure

No management failure (Group 1) included 10 patients.
Possible management failure (Group 2) included 3 patients. Definite management failure (Group 3), included 2 patients and and too little clinical information (Group 4) was available in 3 patients.
Table 7 shows the prevalence of preoperative co-morbidity, which included malignancy, cardiovascular and respiratory disease. Another three patients had purulent or faecal peritonitis been present for more than 48 h. One patient was being treated with methotrexate for severe rheumatoid arthritis, and one patient had severe Parkinson's disease.

Discussion

This study has shown that acute complications of diverticular disease of the sigmoid colon needing surgical treatment carry a high morbidity and substantial mortality. This study has also shown that to a large extent mortality and morbidity is driven by patient related factors as expressed by elevated physical severity scores and lack of peri-operative management failures in the majority of deceased patients.

Although comparison of surgical outcome is desperately needed, this is difficult because interstudy differences are too great, including the definition of indications for acute surgery, the proportion of patients with Hinchey stages III and IV, lack of information on how ill patients were when they came to surgery, i.e. lack of accurate patient risk stratification, proper definition of acute surgery and lack of detailed information on morbidity [17-22].

There is abundant evidence from the literature to show that mortality for Hinchey I and II patients is substantially lower than for Hinchey III and IV patients [23-35] (Table 8). Surgical common sense dictates that patients with faecal peritonitis fare worse than those patients with localized abscesses or isolated meso-colonic phlegmon. Many authors have only given data on the Hinchey classification and have used it as a means to explain morbidity and mortality differences. The Hinchey classification however, is a system, which only classifies the severity of the intra-abdominal insult and not the systemic response by the patient [10]. The nature of this response is furthermore dictated by the co-morbidity

of the patient. When Krukowski & Matheson [24] reviewed the literature in 1984 a mortality rate of 21.4% for Hinchey III and IV patients was found similar to the mortality rate of 21.3% in the current study (Table 8). While the timing of surgery for Hinchey stages III and IV is well defined this is less so for Hinchey stages I and II. Comparison of mortality data is therefore difficult in the latter group. The patients in the present study were all operated on an acute to urgent basis. None was operated on semi-electively after an acute episode of diverticulitis that had responded to conservative therapy. In such patients residual diverticulitis may have been reported by the pathologist, which would then place these elective patients in Hinchey I. These patients would have had the choice to accept or refuse surgery whereas the clinical situation of all patients in the present study demanded surgical intervention.
Although more patients died in the Hinchey III / IV group there was no significant relation between Hinchey classification and post-operative mortality. This may be due to the relative small sample size in this study, in which the mortality rates for Hinchey III/IV were well within the limits of the literature (Table 8). This suggests that overall management of these critically ill patients had been similar to other centres. The high mortality of 13.4% in Hinchey I/II was well above the average of 1.5-2% reported in the literature (Table 8). An explanation could be that the definition of acute surgery was different in this study. In addition, however, patient risk factors may have contributed and this is made clear as shown by the POSSUM scores in Table 7.
The POSSUM (Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity) scoring system was developed by Copeland *et al.* [11] in 1991 to predict risk-adjusted morbidity and mortality between patients groups with different case mix. It uses a 12 factor, four grades, physiological score (PS) and a 6 factor, four grades, operative severity score (OSS). Whether or not the POSSUM scoring system needs adjustment in specific types of surgery remains a matter for debate [12,13,36-40]. The original POSSUM scoring system seems nevertheless to be the most appropriate for comparison of surgical outcome and has been validated for colorectal surgery [18,20,40,41]. Thus the mortality of 13.4% for patients with Hinchey stages I and II was in line with the POSSUM predicted mortality (p.p.m.) of 19.4% for these patients (Table 9). This means that a number of patients with Hinchey I/II have severe comorbidity and therefore higher p.p.m. rates. This was the case in our study because some 40% had a p.p.m. of over 10% and some 19% of Hinchey I/II patients had a p.p.m. of more than 20%. When mortality rates for surgical treatment of acute complications of sigmoid diverticulitis are to be compared the timing of surgery and the risk stratification of patients as well as Hinchey stage should be considered.
Because this information is not present in many studies it is not possible at

present to compare mortality data.
Besides this mortality, morbidity is also high. The most frequent complications are infectious or cardiac. In these often critically ill patients however, many other complications occur, that may require re-operation. In line with recent data [28,30-32] anastomotic leakage occurred in 20% of patients having resection and anastomosis in the present study. The debate on whether primary anastomosis is safe in these patients has put too much emphasis on the Hinchey classification. The Mannheim peritonitis index, which includes the state of the patient to some extent, should give a better assessment of risk [42]. The question of whether or not to perform primary anastomosis needs to be addressed urgently by a randomized trial with proper risk stratification of patients.

Besides re-operations some patients will need secondary elective surgery. Reversal of a Hartmann procedure, which was successful in 90% of patients in this study, or incisional hernia surgery are the most common secondary procedures. These bring with them additional morbidity and some mortality albeit low.

Definite management failures were identified in two patients and possible management failures in three patients. The clinical course would very likely have been different without them. There were however, no management failures in most of the patients with severe co-morbidity (Table 7). How can these results be improved? Peri-operative management, with intensive preoperative preparation even for a longer period than is currently the case may be one approach. There are no data on the possible influence of a specialized colorectal unit in reducing morbidity and mortality. Another approach would be to identify those patients at risk of developing acute diverticular complications before they occur and offer them prophylactic elective surgery.
Mortality and morbidity of surgery for acute complications of sigmoid diverticulitis is high and is dictated more by the general condition of the patient than by the extent of peritoneal involvement.

Table 1 Type and definition of post-operative complications

	Assigned number in registration
Deep wound infection: mandatory lay open of the wound	1
Intra-abdominal abscess: confirmed by laparotomy or percutaneous drainage (CT or sonography guided)	2
Anastomotic leak: confirmed by intraluminal contrast studies and/or laparotomy	3
Bleeding or significant wound haematoma	4
Pulmonary: confirmed by chest X-ray and/or mucus cultures	5
Thrombosis and/or pulmonary emboli: confirmed by venography, duplex sonography, ventilation/perfusion scans and/or CTA	6
Pressure ulcer	7
Urinary tract: positive urine cultures mandatory	8
Cardiac: electrocardiography and or CK/CKMB mandatory for ischemic disease, or by X-thorax for congestive heart failure	9
Central nervous system: Intra-cerebral events confirmed by CT scan	10
Sepsis: confirmed by blood cultures	11
Miscellaneous	12
Multiple organ failure	13

Table 2 Indication, type of surgery and Hinchey classification

Operation indication	Type of operation	Hinchey I-II No. of patients	Hinchey III-IV No. of patients	Total No. of patients
Perforation or peritonitis (n =62)	Resection and anastomosis	4	1	5
	Colostomy	2	1	3
	Hartmann	15	39	54
colonic obstruction (n =24)	Resection and anastomosis	2		2
	Colostomy	5		5
	Hartmann	11	6	17
Failed conservative treatment (n =28)	Resection and anastomosis	14		14
	Colostomy	4		4
	Hartmann	10		10
Total		67	47	114

Table 3 Post-operative complications

Type of complication	Complications
Wound infection	12%
Intra-abdominal abscess	5%
Anastomotic leak	4(23.8)%*
Rebleeding/haematoma	4%
Pulmonary infection	33%
Thrombo-embolic	6%
Pressure sores	4%
Urinary tract	37%
Cardiac	12%
Central nervous system	4%
Sepsis	10%
Miscellaneous	23%
Multiple organ failure.	2%

*Numbers in parentheses were calculated for the resection and anastomosis group only

Table 4 Type and number of re-operations

Type re-operation	No of operations
Laparotomy for ongoing sepsis	25
Hartmann's procedure	2
Revision colostomy	1
Cholecystectomy and choledochotomy	1
Ruptured abdominal aneurysma	1
Septic gonarthritis	1
Splenectomy	1
Woundehiscence	1
Woundexcision	1
Thiersch graft	1

Table 5 Morbidity non-survivors *vs.* survivors

Type complication	Non-survivors percentage of complications	Survivors percentage of complications	*P* value χ^2
Wound infection	0%	14.7%	0.122
Intra-abdominal abscess	5.3%	5.3%	1.000
Anastomotic leak	10.5 (50.0)%*	3.2(17.6)%*	0.193 (0.231)*
Bleeding/haematoma	5.3%	3.2%	0.523
Pulmonary infection	57.9%	28.4%	0.013
Thrombo-embolic	10.5%	5.3%	0.330
Pressure sores	0%	4.2%	1.000
Urinary tract	36.8%	36.8%	1.000
Cardiac	36.8%	7.4%	<0. 001
Central nervous system	5.3%	3.2%	0.523
Sepsis	42.1%	3.2%	<0. 001
Miscellaneous	42.1%	18.9%	0.038
Multiple organ failure.	10.5%	0%	0.027

*Numbers in parentheses only calculated for the resection and anastomosis group.

Table 6 POSSUM stratification, predicted number and observed number of deaths

PPM Risk group %	No. of patients	PPM Predicted number of deaths	Observed number of deaths
<5	8	0.3	1
5-<10	14	1	0
10-<20	30	4.4	4
≥20	62	28.3	14
Total	114	30.4	19

PPM is POSSUM Predicted Mortality

Table 7 Clinical details of deceased patients

Gender	Age years	POSSUM predicted mortality (%)	Hinchey Classification	Complications * (days in hospital)	Co-morbidity
F	81	85	III	5,6,8,9,12 (13)	Congestive heart failure
F	70	35	II	5,9 (9)	COPD, Methotrexate for Rheumatoid arthritis
F	63	44	III	11 (2)	Metastasised lung carcinoma
M	61	11	II	2,5,8,12 (33)	Metastasised prostate
				10 (6)	carcinoma
F	84	11	I	6,	Died from CVA
F	80	68	IV	8,9 (27)	Congestive heart failure, end stage liver cirrhosis
F	84	59	II	11,12 (2)	Congestive heart failure, Rheumatoid arthritis
M	83	94	III	5 (5)	COPD, cardiomyopathy
F	82	71	III	11 (16)	SLE with renal damage,
F					congestive heart failure
	83	89	IV	9,11 (1)	Liver abscesses
F	84	26	III	5,9 (37)	M.Crohn and masked peritonitis
M	80	79	III	12 (2)	Metastasised lung carcinoma
M	82	87	III	9,12 (15)	Prostate carcinoma
F	71	40	III	5,9 (6)	Metastasised breast carcinoma
F	76	10	II	5 (1)	End stage M.Parkinson
M	75	67	III	4,5,8,11 (6)	None
F	67	20	I	3,5,8,11,13 (9)	Chemotherapy for metastasised lung carcinoma
F	64	28	I	5,8,11,12 (5)	None
M	57	3	II	3,5,8,11,13 (22)	None

* Numbers refer to table 1

Table 8 Mortality rates Hinchey I/II and Hichey III/IV diverticulits

Author	Year	Number of patients	Mortality overall %	Mortality Hinchey I/II %	Mortality Hinchey III/IV %
Rodkey [23]	1984	200	6.5	3.8 (183)	35.3 (17)
Rodkey [23]	1984	269	7.8	4.6 (218)	21.6 (51)
Krukowski [24]	1984	1292			21.4
Krukowski[25]	1985	21	14.3	0.0 (11)	30.0 (10)
Greg[26]	1987	140	5.0		
Kronborg[27]	1993	62		-	22.6 (62)
Tudor[28]	1994	175	16.0	7.7 (117)	32.8 (58)
Wedell[29]	1997	56	14.3	3.2 (31)	28.0 (25)
Hoemke[30]	1999	113	2.7	1.9 (103)	10.0 (10)
Zeitoun[31]	2000	99		-	22.2 (99)
Gooszen[32]	2001	45	6.7	(35)	(10)
Schilling[33]	2001	55			9.1 (55)
Blair[34]	2002	33	9.1	4.2 (24)	22.2 (9)
Biondo[35]	2002	83	26.5	(28)	(55)
Present study		114	16.7	13.4 (67)	21.3 (47)

Number in parentheses is number of patients per Hinchey group

Table 9 Observed and POSSUM predicted mortality

Risk group	No. of patients	PPM Predicted deaths No. of patients	Observed deaths No. of patients
Hinchey I/II	67	13 (19.4%)	9 (13.4%)
Hinchey III/IV	47	22 (46.8%)	10 (21.3%)

PPM is POSSUM predicted mortality

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Chapter 4

Reversal of Hartmann's Procedure After Surgery for Complications of Diverticular Disease of the Sigmoid Colon is safe and possible in Most Patients

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Abstract

Background:

Although evidence is growing that most patients who need an operation for diverticular disease of the sigmoid colon can be treated by a single-stage procedure, a two-stage procedure will still be necessary in some patients because of significant sepsis or technical difficulties. The outcomes of 65 patients who underwent secondary restoration after a Hartmann procedure for complicated diverticulitis were studied and the factors leading to complications and mortality were identified.

Patients and Methods:

Of 91 patients, in a consecutive 12-year period, whose primary operation was a Hartmann procedure, 72 survived longer than three months after discharge. Sixty-five underwent an attempted reversal of the Hartmann procedure. The POSSUM scores were calculated in all patients as well as the morbidity and mortality rates.

Results:

In 63 (96.9%) patients the bowel continuity could be restored with a morbidity of 38.5% and a mortality of 3.1%. The Possum and p-Possum score predicted adequately the mortality in this series.

Conclusion:

This series shows that when surgical treatment for complicated diverticular disease of the sigmoid colon is necessary the Hartmann procedure is still a valid indication. In a high percentage of patients the Hartmann procedure could be restored with a low mortality.

INTRODUCTION

Diverticulosis of the sigmoid colon is a common and increasing condition in the Western population and is estimated to occur from less than 10 % in those younger than 40 years old to an estimated 50% to 66% of patients older than 80 years [1,2]. Although it is not possible to predict the likelihood of serious complications, 10% to 25% of patients with diverticulosis will have complications [3].

When hospital admission is necessary, 24% to 29% of patients need an operation during the same hospital admission. And after successful conservative treatment of the first attack of diverticulitis, another 2% to 26% will also be operated on for recurrent diverticulitis in their live. In total about 34% to 48% of the patients who needed a hospital admission an acute or elective operation for their diverticulitis was necessary [4-8]. The incidence of perforation of sigmoid diverticulosis in the population is increasing but still low, with a yearly rate of 3.8 to 4.0 cases per 100,000 [9,10].

A two-staged procedure, usually as described by Hartmann [11,12], has until recently been the most common for treating patients who require emergency surgery for complicated diverticular disease of the sigmoid colon [5-10, 13-16] but is also used when technical difficulties are encountered in electively operated on patients [17, 18].

In addition to the disadvantages of extra hospital admissions, the Hartmann procedure results in an often demanding restoration of bowel continuity and the fear of extra mortality, in addition to reports that 13% to 69% of patients will be left with a permanent stoma [19-21]. However, the literature is diverse and not conclusive. Most series are small and combine the Hartmann procedure for diverticulitis, carcinoma and miscellaneous situations. Reversal after a carcinoma procedure is less frequently performed (4% to 35%), in contrast with diverticular disease where in 31% to 85% the bowel continuity is restored [7, 19, 20, 22-31]. Although there is growing evidence that patients who need an acute operation for diverticular complications of the sigmoid colon can be cured with a single-stage procedure [14, 21, 32], with or without a diverting ileostomy, a Hartmann procedure is still indicated as primary operation in patients because of technical difficulties, faecal peritonitis, or haemodynamic instability.

We studied the outcomes of all patients, who survived after a primary acute or elective Hartmann procedure for diverticulitis of the sigmoid colon in a consecutive 12-year period. The aims of this study were to evaluate the rate of reversal in this group of survivors, and to investigate if reversal can be performed with an acceptable mortality and morbidity.

Patients and Methods

Database

From 1990 to 2002, a prospective computerized morbidity and mortality registration was done for all patients admitted to the surgical wards by one of the authors (JLT Oomen). A total of 263 patients underwent surgery on the sigmoid colon for complicated diverticular disease and were included in the study. Out of 114 patients who underwent an acute primary operation a Hartmann procedure was performed in 81 patients. Out of 149 elective patients, 139 patients underwent primary resection and anastomosis and 10 patients underwent a Hartmann procedure. Indications for and type of primary surgery in the acute group of patients and in the elective group of patients are described in tables 1 and 2.

Fourteen patients died in-hospital after an acute Hartmann procedure, and 1 patient died after an elective Hartmann procedure. Within 3 months after discharge from hospital, another 4 patients, who had undergone an acute Hartmann procedure, died from causes unrelated to diverticulitis. Therefore 72 patients survived their primary operation and were eligible for reversal of a Hartmann procedure. In 65 patients an attempt at restoration of bowel continuity was made and in 7 patients no attempt was made for reasons outlined in table 3.

Type of surgery

Hartmann procedure: resection of the diseased sigmoid, closure of the distal part, and end-colostomy of the proximal colon.

Primary surgery: first operation (acute or elective) for diverticular disease of the sigmoid colon.

Secondary surgery: second-stage operation on the sigmoid colon, after discharge from the primary surgery.

Re-operation: any re-operation during the original hospital admission.

Risk stratification of patients

The Physiologic and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) scoring system was used to identify patient-related risk factors to provide an objective measure to assess morbidity and mortality data [33-35]. The physiologic score (PS) and operative severity score (OSS) were calculated for each patient. The data necessary to calculate the POSSUM score were retrospectively collected by one of the authors (JLT Oomen), and 97.4% of the data were found (PS, 97.8%; OSS, 96.4%).

To audit patient deaths, linear regression methods as described by Whiteley [36],

Prytherch *et al.* [37] and recently by Bennett-Gerrero *et al.* [38], Lam *et al.* [39] and Mohil *et al.* [40] were used.
The POSSUM and p-POSSUM [37] formula was used to calculate expected mortality for each patient and allowed us to stratify groups.
Four bands of increasing POSSUM and p-POSSUM predicted mortality were examined: 0% to <5% (group I), 5% to <10% (group II), 10 to <20% (group III), and $\geq$ 20% (group IV). Predicted mortality was compared with the observed death rate in each group.

COMPLICATIONS

Complications that were registered are listed in Table 4.

STATISTICAL ANALYSIS

Data were analysed with the Statistical Package for the Social Sciences (SPSS) software (verse 9.0, SPSS, Chicago, IL). The Pearson chi-square test, Fisher exact test and Student *t*-test for equality of means were used when appropriate. Significance was evaluated at $P = 0.05$.

RESULTS

The 65 patients had an averaged age of 62 years (range, 29 to 89), and 33 (50.8%) were men. Women were older ($P = 0.049$) than men but no further statistical differences were found between men and women in this study.

TYPE OF SURGERY

In 63 (96.9%) of 65 patients, restoration of bowel continuity was successful. In 11 patients, more than one procedure was done during the same operation: resection of small intestine (n =1), resection of the left colon (n =1), appendectomy (n =2), repair of inguinal hernia (n =1), repair of incisional hernia (n =3) and covering transverse colostomy (n =3). The latter patients had their covering colostomy closed on a separate occasion without further mortality or morbidity. In two patients, it was impossible to restore the Hartmann procedure due to technical reasons. One patient, an 84-year-old woman, had extensive adhesions after an acute operation for perforated diverticulitis (Hinchey III, [41]). In another patient, an 82-year-old woman, who underwent primary surgery for recurrent complicated diverticulitis (Hinchey II), pelvic abscesses were found and drained during the second operation.

POSSUM SCORE

The mean PS was 17.0 (range, 12 to 33), and the mean OSS was 12.5 (range, 9 to 23). The POSSUM scores did not differ significantly between the male and female patients: PS: male/female, 17.1/17.0 (P= 0.936), OSS: male/female, 12.2/13.0 (P=0.336), POSSUM total: male/female, 29.3/29.9 (P= 0.638).

MORBIDITY

Patients whose general condition demanded intensive treatment and patients with serious post-operative complications were cared for in a dedicated intensive care setting that did not change during the study period. At least one complication developed in 25 patients (38.5%) and 11 patients (16.9%) developed two or more complications. After exclusion of urinary tract infections related to indwelling urinary catheters, morbidity rate was still 24.6%. The type and frequency of post-operative complications are listed in table 4.

Older patients had a higher PS (P= 0.028) and more complications (P= 0.043). Also women suffered more urinary tract complications (P= 0.006) than men. Patients with complications needed more re-operations during their hospital admission (P< 0.001).

Three patients suffered anastomotic leaks. One patient was successfully treated conservatively and the other patients were treated by a transverse colostomy and drainage.

Eleven patients (16.9%) underwent a variety of re-operations: 7 patients had 1 re-operation, 2 patients had 2 re-operations, 1 patient had 3 re-operations, and 1 patient had 6 re-operations. Of 6 patients who needed a colostomy during re-operation for complications, 1 patient died and 5 patients had their colostomy reversed during a separate admission without mortality.

MORTALITY

Two patients died, for a 3.1% in-hospital mortality rate. One female patient aged 89, with end-stage dementia, underwent reversal of Hartmann's procedure for severe stoma problems. Post-operatively she developed an intra-abdominal abscess because of retained gauze. Subsequently she developed sepsis, cardiac complications as well as urinary tract and pulmonary infections. She died on the 28th post-operative day. One male patient aged 54 developed an intra-abdominal abscess, sepsis and multiple organ failure. After six relaparotomies, he died on the 37th post-operative day.

No differences were found between mortality and gender (P=1.000), age (P=0.297), PS (P=0.195) or OSS (P=0.988).

For each nonsurvivor, a POSSUM and p-POSSUM-predicted mortality was calculated, and patients were allocated to 1 of 4 risk groups (see Methods). For each risk group, the predicted and observed number of deaths was calculated. The Possum and p-POSSUM equation predicted adequately the mortality in this series. Data are listed in Table 5.

DISCUSSION

Surgical treatment of complicated diverticulitis should ideally consist of removing the diseased sigmoid, with restoration of continuity and the lowest possible mortality and morbidity. Especially in the presence of generalized peritonitis, it is no longer debated that direct post-operative mortality and morbidity will be lower when the septic focus is eliminated in the primary operation [42-43]. Although restoration of bowel continuity is important, it remains a secondary to the most important goal: patient survival.

Still being debated is in which patients, after resection, a primary anastomosis is safe to perform. Alternatives for the Hartmann procedure include resection and primary anastomosis, with or without a temporary loop ileostomy or loop colostomy. However Gooszen *et al.* [44] have shown that temporary decompression after colorectal surgery for various indications carries a high complication rate with a considerable associated mortality. Their mortality of 3.3% after stoma closure was the same as in our series. The classic 3-stage procedure is very poorly tolerated and is therefore hardly ever used.

Some authors have described the emergency surgical situation of the left bowel treated by primary anastomosis without a decompressing colostomy. The safety of this treatment compared with the Hartmann or other surgical procedures has never been adequately studied however and the patient groups are small and highly selected, which explains the reasonable rate of mortality and morbidity.

In a prospective study of 45 patients, Gooszen *et al.* [21] found that primary resection and anastomosis was safe in acute, non-obstructive cases of complicated diverticular disease with a Hinchey I-IV classification.

Schilling *et al.* [14], Biondo *et al.* [32] and Blair *et al.* [15] showed in retrospective studies that safe primary resection and anastomosis is possible in patients with severe peritonitis. However, patient selection for primary anastomosis in these studies proved to be mostly subjective and was left to the discretion of the surgeon at call, who considered such variables as the patient's haemodynamic condition, status of the abdomen, blood supply of the bowel and experience of the operating team.

A recent survey among all surgical members of the Dutch Society of Gastro-Intestinal Surgery revealed that most surgeons considered the Hartmann procedure the optimal treatment for complicated left-sided bowel disease when the clinical situation is compromised, such as in older patients, diffuse peritonitis or diffuse faecal contamination [45]. There was, however, no consensus for clinical situations that were less severe such as in younger patients or those with localized disease.

Salem and Flum [46] reviewed the literature to summarize and compare the reported outcomes of one stage and two stages operations for the treatment of perforated diverticulitis with peritonitis Hinchey stages III-IV. Reported mortality and morbidity in patients who underwent primary anastomosis were not higher than in patients undergoing Hartmann's procedure were. However selection bias may have been a limitation and a prospective randomized trial is recommended.

In the absence of large, randomized, prospective studies, many surgeons still prefer multistage procedures in complicated situations, especially in the presence of generalized peritonitis or obstruction. Disadvantages of multistage procedures are the need for re-intervention, with possible mortality, and in the case of a Hartmann procedure, a demanding operation. In the literature, 13% to 69% of these patients operated on for complicated diverticular disease are left with a permanent stoma [7, 20, 22-25]. In our series, reversal was attempted in 65 patients (90%) and was successful in 63 patients (96.9%). Moreover, morbidity in this study was 38.5%, and the overall mortality after reversal of the Hartmann was 3.1%, which is concordant with the literature. Despite the low number of deceased patients, the POSSUM and p-POSSUM score resulted in a similar predicted and obtained mortality.

This study has shown that reversal of a Hartmann procedure after complicated diverticulitis (acute or elective) is possible in the majority of patients. Whether a mortality rate of 3.1% associated with this procedure outweighs increased mortality should a Hartmann procedure not have been performed at primary surgery remains a matter for debate. Severe complicated diverticular disease may well remain a valid indication to perform a Hartmann procedure.

Table 1 Indication, type of surgery and Hinchey classification in acute patients

Operation indication	Type of operation	Hinchey I-II No. of patients	Hinchey III-IV No. of patients	No. of patients
Perforation or peritonitis (n =62)	Resection and anastomosis	4	1	5
	Colostomy	2	1	3
	Hartmann	15	39	54
Colonic obstruction (n =24)	Resection and anastomosis	2		2
	Colostomy	5		5
	Hartmann	11	6	17
Failed conservative treatment (n =28)	Resection and anastomosis	14*		14
	Colostomy	4		4
	Hartmann	10		10
Total		67	47	114

* 2 with covering stoma

Table 2 Indication and type of surgery in elective patients

Operation indication	Hartmann	Resection and anastomosis	No. of patients
Fistula		2	
Colo-vesical	4	1*	25
Colo-entero-vesical		1	1
Colo-vaginal	1	1	2
Previous septic complications			
Liver abcess		2	2
Pelvic abcess		3	3
E-coli sepsis		1	1
Recurrent diverticulitis	5	54**	59
Stenosis		32	32
Functional complaints		22	22
Bleeding		2	2
Total	10	139	149

* 1 patient with covering stoma, ** 5 patients with covering stoma

Table 3 Patients not reconstructed

Gender	Age (years)	Acute primary operation	Hinchey stage at primary operation	Remarks
Female	55	No	I/II	Severe obesity and COPD. Primary anastomosis not possible; >1000 mL blood loss during operation. Complications: deep wound infection, pressure ulcers, urinary tract infection.
Female	71	Yes	I/II	Complications: urinary tract infection. Died 1-year post-operatively from pulmonary disease.
Female	82	Yes	III/IV	Complications: intra-abdominal abscess, pulmonary, pressure ulcers, urinary infection. 2x relaparotomy with splenectomy.
Female	79	Yes	III/IV	Complications: urinary tract infection. Cardiac history.
Female	81	Yes	III/IV	Complications: urinary tract infection. Cardiac history.
Female	79	Yes	III/IV	Complications: deep wound infection, pulmonary and congestive heart failure. Cardiac history.
Male	67	Yes	I/II	Preoperatively liver abscesses were drained. Complications: pulmonary, thrombosis, line sepsis. Laparostomy primarily and re-operation for closure.

COPD, chronic obstructive pulmonary disease

Table 4 Type and frequency of post-operative complications

Complication	Total (%)
Deep wound infection	6.2%
Intra-abdominal abscess	6.2%
Anastomotic leak	4.8%*
Re-bleeding/haematoma	1.5%
Respiratory infections	6.2%
Thrombo-embolism	1.5%
Urinary tract infections	27.7%
Cardiac	1.5%
Sepsis	3.1%
Miscellaneous	13.8%
Multiple organ failure	1.5%

* Calculated for the restored group

Table 5 POSSUM and p-POSSUM stratification, predicted number and observed number of deaths

PPM (%)	No. of patients		Predicted number of deaths		Observed number of deaths	
	Possum	p-Possum	Possum	p-Possum	Possum	p-Possum
<5	32	61	1	1	0	2
5-<10	21	2	1.5	0.1	1	0
10-<20	8	0	0.9	0	1	0
≥20	4	2	1.5	0.6	0	0

PPM: POSSUM and p-POSSUM Predicted Mortality.

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Chapter 5

A Comparison of Outcome of POSSUM, p-POSSUM and cr-POSSUM Scoring After Elective Resection of the Sigmoid Colon for Carcinoma or Complicated Diverticulitis

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ABSTRACT

Background :

The aim of this study was to compare the predicted mortality calculated by using the Physiologic (PS) and Operative Severity score (OSS) for the eNumeration of Mortality and morbidity (POSSUM), the p-POSSUM, and the cr-POSSUM equation, with the observed in-hospital mortality in patients undergoing elective sigmoid colectomy for diverticulitis or carcinoma.

Methods:

From 1990 to 2002, 241 patients were studied, 120 with a carcinoma and 121 with diverticulitis. The POSSUM and cr-POSSUM scoring system was used for each patient to identify patient- or disease-related risk factors. The POSSUM, p-POSSUM, and cr-POSSUM formulas were used to calculate expected mortality for each patient, and from this, the average predicted mortality for each group was calculated.

Results:

Patients with a carcinoma were significantly older ($P = 0.002$) and had higher PS ($P = 0.015$) and cr-PS ($P = 0.004$), OSS ($P < 0.001$) and cr-OSS ($P < 0.001$) scores, but their observed mortality (1.7%) was lower than in the diverticulitis group (3.3%). In contrast, all POSSUM systems predicted higher mortalities in the carcinoma group. The POSSUM equation overpredicted mortality with an observed:expected (O:E) ratio overall of 0.30. The the p-POSSUM and cr-POSSUM equations predicted overall mortality more accurately, with both an O:E ratio of 0.83. Eliminating the score for malignancy and replacing it with a minimum score of 1 gave overall O:E ratios of 0.37 (POSSUM), 1.04 (p-POSSUM), and 0.93 (cr-POSSUM).

Conclusion:

In patients who underwent elective resection of the sigmoid colon for carcinoma or diverticulitis, the p-POSSUM and cr-POSSUM scores predicted the observed mortality accurately, especially when used without a score for malignancy.

INTRODUCTION

Audit of outcome has become an important part of surgical practice and has lead to an increasing number of papers on this topic. Most authors point out that crude rates of mortality are inadequate for medical audits or comparisons among individual hospitals, surgical units, or surgeons. This can be misleading and may lead to erroneous conclusions because of different patient mix. Although one of the current controversies is whether a relationship exists between volume and outcome, an adequate risk adjustment is necessary beforehand to obtain a meaningful comparison among groups.

Several papers in the recent literature compare post-operative morbidity and mortality outcomes among different surgical units, individual surgeons, or specified diseases by using risk scoring systems, especially the Physiologic (PS) and Operative Severity score (OSS) for the eNumeration of Mortality and morbidity (POSSUM) 1 and p-POSSUM 2 model. This method has been generally validated in gastrointestinal 3 and, more specifically, in elective and acute colorectal surgery for different diseases.4-5

A lack of calibration at the extremes of age and high emergency workload was found in patients undergoing colorectal surgery, however.6 This has lead to the development of a dedicated scoring for colorectal surgery for all indications, the colorectal POSSUM (cr-POSSUM),7 which now needs further validation. Colon cancer resections in the United States recently showed that all three POSSUM variants overpredicted mortality.8

This study was conducted to compare mortalities predicted by the POSSUM, p-POSSUM, and cr-POSSUM with the observed in-hospital mortality in a group of patients who underwent elective resection of the sigmoid colon for carcinoma or complicated diverticular disease.

PATIENTS AND METHODS

DATABASE

From 1990 to 2002, a prospective computerized morbidity and mortality registration was done for all patients admitted to the surgical department by one of the authors (JLT Oomen). Patients who underwent major acute or elective surgery on the colorectum were identified. Patients who needed more than one operation in a new hospital admission were considered to be a new patient for every operation they underwent. The completeness of the database and the mortality figures was validated by comparing them with the Dutch National

Medical Registry (Prismant). The validity of the Prismant data collection has been the subject of a large national study in which a correct administrative coding was obtained in more than 95% of patients.[9] Our database had complete agreement between mortality numbers and only a 0.4% difference in the number of colorectal resections performed. Table 1 shows the crude number, type of operations, mortality, and morbidity figures.

From this database of 1604 patients, all patients who underwent elective resection of the sigmoid colon for carcinoma or complicated diverticular disease were isolated. A total of 241 patients were found (mean age, 65.9 years; range, 30.6-88.8); 108 patients were men (mean age, 65.4 years) and 133 were women (mean age, 66.4 years). There were 120 patients (64 men, 56 women; mean age, 68.1 years; range, 42.0-87.6) with a carcinoma of the sigmoid colon and 121 (44 men, 77 women; mean age, 63.8 years; range, 30.6-88.8) were operated on for diverticular disease. All patients had colon carcinoma or different forms of diverticular disease confirmed by a post-operative histologic examination. Patients with both diseases were listed in the carcinoma group.

INDICATIONS FOR SURGERY

Indications for surgery were (1) suspected or histologic confirmed carcinoma of the sigmoid colon and (2) complicated diverticular disease of the sigmoid colon with fistulas in 22, recurrent attacks of diverticulitis (with or without abscesses) in 56, functional complaints in 14, bleeding in 2, or stenosis in 27. In the carcinoma group, the Dukes (Turnbull) staging was as follows; Dukes A in 32 patients, Dukes B in 29, Dukes C in 37, and Dukes D in 22 patients.

TYPE OF SURGERY

Sigmoid resection was defined as resection, through a midline laparotomy, of the sigmoid loop from the descending colon to the sigmoid-rectal junction at the level of the promontory, followed by primary anastomosis. A group of nonspecialized general surgeons performed all operations.

RISK ADJUSTMENT

Risk adjustment was performed by the POSSUM, p-POSSUM, and cr-POSSUM system, which also have a score for malignancy. The items of the POSSUM scoring system were used to identify patient-, operation-, and disease-related risk factors to provide an objective measure to assess morbidity and mortality data.

This system uses a 12-factor, 4-grade physiologic score (PS) (Table 2) and a 6-factor, 4-grade operative severity score (OSS) (Table 3), from which expected mortality and morbidity can be calculated. The p-POSSUM score uses the same variables but has a different equilibration for the calculation of mortality and no formula for morbidity. In the cr-POSSUM scoring system (Table 4), 10 of the original 18 factors of the POSSUM scoring system are used and have also no formula for morbidity.

The author (JLTO) retrospectively collected the data necessary to calculate the POSSUM score. In total, 96.3% of the values could be found (95.1% of the PS and 98.9 % of the OSS). Missing data were replaced by the average of the found data per type of indication, which left the statistical calculations unaffected.

With the POSSUM, p-POSSUM, and cr-POSSUM equilibrations (Table 5), the predicted mortalities for each patient and the average predicted mortality for each group are calculated and compared with the observed mortality.

COMPLICATIONS

Complications that were registered prospectively are listed in Table 6.

STATISTICAL ANALYSIS

Data were analyzed using SPSS software (version 9.0) (SPSS Inc., Chicago, IL) for Windows (Microsoft, Redmond, WA). The Pearson chi-square test, Fisher exact test, and Student *t*-test for equality of means were used when appropriate. Significance was evaluated at $p = 0.05$.

RESULTS

TYPE OF SURGERY

A sigmoid resection and primary anastomosis was performed in all patients. In 6 (2.5%) of the 241 patients, a protecting transverse loop colostomy was created, 5 in the diverticulitis group and 1 in the cancer group ($p = 0.213$). In 46 patients, more than one operation was done during the first procedure. Data on these extra operations are given in Table 7. There were no differences between more than one primary operation and gender ($p = 0.874$), age ($p = 0.256$), PS ($p = 0.790$), cr-PS ($p=0.909$), or malignancy ($p = 0.208$). Patients with more than one primary operation had a higher OSS ($p < 0.001$).

GENDER

In the whole group, women had more complications ($p < 0.001$) because of more urinary tract infections ($p < 0.001$). There was no difference between gender and fistulae ($p = 0.638$) or fistulae and urinary tract infection ($p = 0.842$). Men had more cancer ($p = 0.008$). There were no statistical differences between gender and age ($p = 0.487$), more than one primary operation ($p = 0.874$), PS ($p = 0.922$), cr-PS ($p=0.171$), or OSS ($p = 0.370$), cr-OSS ($p=0.213$) and mortality ($p = 0.576$).

Malignancy/benign disease

Patients with a carcinoma were older ($p = 0.002$) and had a higher PS ($p = 0.015$), cr-PS (p=0.004), OSS ($p < 0.001$), and cr-OSS ($p < 0.001$) than did the diverticulitis group. The higher OSS and cr-OSS were due to the score for malignancy (both $p < 0.001$); whereas the significantly higher PS and cr-PS were due to age ($p = 0.005$ and p=0.003) and a lower hemoglobin level ($p = 0.013$ and $p = 0.034$). Mortality ($p = 0.684$), complications ($p = 0.175$), and operative procedures did not differ significantly between the two groups. Data are depicted in Table 8.

POSSUM scoring

In the whole group, the average POSSUM score was 30.1(PS, 17.5; OSS, 12.6). In the carcinoma group, this was 32.1 (PS, 18.3; OSS, 13.8) and it was 28.2 (PS, 16.7, OSS, 11.5) in the diverticulitis group. These differences are significant (POSSUM score, $p < 0.001$; PS, $p = 0.015$; and OSS, $p < 0.001$) between the two groups. In the PS, significant factors were age ($p = 0.005$) and hemoglobin level ($p = 0.013$), whereas in the OSS, only malignancy was a significant factor ($p < 0.001$).

cr-POSSUM scoring

In the whole group, the average cr-POSSUM score was 16.3 (cr-PS, 8.9; cr-OSS, 7.35). In the carcinoma group, this was 17.1 (cr-PS, 9.4; cr-OSS, 7.7), and it was 15.5 (cr-PS, 8.5; cr-OSS, 7.0) in the diverticulitis group. These differences are significant between the two groups (cr-POSSUM score, $p < 0.001$; cr-PS, $p = 0.004$; and cr-OSS, $p < 0.001$). In the cr- PS, significant factors were age ($p = 0.003$) and hemoglobin level ($p = 0.034$), whereas in the cr-OSS, only malignancy was a significant factor ($p < 0.001$).

Morbidity

The complication rate was 44.8% in men and 55.2% in women ($p < 0.001$) for an overall rate of 47.7%. In the whole group, women had more complications ($p < 0.001$) because of more urinary tract infections ($p < 0.001$). There was no difference, however, between gender and fistulae ($p = 0.638$) or fistulae and urinary tract infection ($p = 0.842$).

Also significant was that more complications were seen in patients who died ($p = 0.009$) and patients who needed reoperations ($p < 0.001$), were older ($p = 0.004$), or had a higher PS ($p = 0.027$) and cr-PS ($p < 0.001$), as well as a higher cr-OSS ($p = 0.018$). Moreover, no significant difference was found in the complications between the carcinoma and diverticulitis group.

The numbers of complications are given in Table 9.

Observed mortality

Six patients (2.5%) died in-hospital. Mortality was 1.9% in the men and 3.0% in the women. The 30-day mortality was 2.5%. Patients with a carcinoma had a mortality of 1.7%, whereas with diverticulitis, it was 3.3%. Patients who died had more complications (p = 0.011), underwent more than one primary operation (p = 0.015), and had higher PS (p = 0.041) and cr-PS (p =0.030) scores. The higher PS and cr-PS scores were due to laboratory values comprising lower hemoglobin (p = 0.015, p=0.036), higher urea (p = 0.006, p=0.007), and in the PS score, an abnormal serum sodium concentration (p = 0.012).

Significant complications in the nonsurvivors were anastomotic leak (p = 0.002), pulmonary infections (p = 0.004), cardiac complications (p = 0.021), sepsis (p < 0.001), multiple organ failure (p = 0.025), and miscellaneous (p = 0.002). No differences were seen between mortality and gender (p = 0.567), malignancy (p = 0.684), age (p = 0.257) or OSS (p = 0.137) or cr-OSS (p = 0.191).

Predicted mortality of POSSUM, p-POSSUM, and cr-POSSUM

The overall POSSUM-predicted mortality was 8.4%, with 10.6% for carcinoma and 6.3% in the diverticulitis group. When the p-POSSUM equation was used, the predicted mortalities were 3.0% overall, with 3.8% for carcinoma and 2.2% for diverticular disease.

The cr-POSSUM-predicted mortalities were overall, 3.0%; carcinoma, 3.8%; and diverticulitis, 2.3%.

Eliminating the score for carcinoma in the OSS and cr-OSS and replacing it with the score for no malignancy (= 1) resulted in the following mortalities overall, for carcinoma, and for diverticulitis: POSSUM, 6.8%, 7.3%, and 6.3%; p-POSSUM, 2.4%, 2.7% and 2.2%; cr-POSSUM, 2.7%, 3.1%, and 2.3%, respectively.

With the above-mentioned percentages, the various O:E death ratios were calculated with and without a score of malignancy. The results are given in Tables10 and 11.

Discussion

It is well recognized that audits of outcomes are of increasing importance in surgical practice. Accurate evaluations of outcomes and standards are needed so that different surgical units and surgeons can be properly compared. Mortality is frequently used as an important and objective measure of outcome, but because crude rates of mortality are not suitable for comparing results, more appropriate scoring systems have been developed for risk adjustment.

In general surgery, the POSSUM scoring system, introduced by Copeland *et al.*[1] in 1991, has proved to be suitable for comparative audits of different processes. To provide an objective method to assess morbidity and mortality data, this system uses a 12-factor 4-grade physiologic score (PS) and a 6-factor 4-grade operative severity score (OSS), from which expected mortality and morbidity can be calculated.

When used in groups of patients consisting of mixed cases, the POSSUM formula has initially seemed to be reliable in general as well as in colorectal surgery, and especially when used to compare variability in crude outcomes for surgical units (Sagar *et al*.,4 1994), or individual surgeons (Copeland *et al*.,10 1995, Sagar *et al*., 5 1996). Using the POSSUM equilibration observed: expected ratios of mortality from 0.83 to 1.06 were found.

However, Whitely *et al*.[11] (1996), and later Prytherch *et al*. [2] (1998), found that the POSSUM score in general surgery overpredicted mortality in the lowest risk patients by a factor of 2 to 7. They recalibrated the original POSSUM equation and developed the p-POSSUM (p=Portsmouth) equation, which uses the same PS, and OSS as described in the POSSUM system.

In a group of patients who underwent major gastrointestinal surgery Tekkes *et al*.[3] (2000) found that the overall POSSUM-predicted mortality was twice the observed one in contrast with the p-POSSUM-predicted mortality, which almost equaled the observed one.

Isbister *et al*. [12] (2002) however found in patients undergoing elective resection for rectal cancer an overprediction in mortality of seven times in the POSSUM formula and more than two times for the p-POSSUM equilibration. In patients who underwent an elective or urgent resection for colorectal cancer, p-POSSUM-predicted mortality was almost twice as high as the observed one. Menon *et al*.[13] (2002).

Nevertheless Wysinge *et al*.[14] (1998) showed in a series of vascular surgery that the O:E death ratios for POSSUM and p-POSSUM were close to unity when the appropriate analysis was performed. Linear analysis for the p-POSSUM system and exponential analysis in the POSSUM score both agreed with the observed mortality.

Tekkis *et al*.[6] (2003) recently demonstrated that in a heterogeneous group of patients who underwent colorectal surgery, the predicted mortality overall matched the observed mortality independently of using the POSSUM or the later-modified p-POSSUM score formula when the right stratification was used. However, subgroup analysis in his series showed that the POSSUM and p-POSSUM equilibrations overpredicted mortality in young patients and underpredicted mortality in patients who were older or had emergency operations.

This lack of calibration in subgroup analysis has lead to the development by Tekkis *et al*.7 (2004) of a dedicated risk-adjustment scoring system for colorectal surgery; the cr-POSSUM, which requires now external validation. Some remarks can be made because it was calculated in a group of patients from which 36%

were proctology and 8% were abdominal operations rather than colorectal. Senagore *et al.*8 (2004) recently showed that in colon cancer resections in the United States all three POSSUM variants overpredicted mortality. However, comparing p-POSSUM risk-adjusted mortality rates in the same risk groups between patients in the United States and the United Kingdom is complicated because in these two cohorts undergoing major, noncardiac surgery, the observed mortality in the United Kingdom was four times higher in the United States cohort (Bennett-Guerrero *et al.*,15 2003).

This suggests that it not can be assumed that POSSUM-based risk-adjusted comparison of outcome of surgery between different countries or health systems are reliable. Specialty- or regional-specific POSSUM-based models might be required to evaluate outcome of surgery, and there is an urgent need for further validation or recalibration of the POSSUM system.

In the series presented here, we studied a cohort that underwent an elective resection of the sigmoid colon for carcinoma or complicated diverticular disease, calculated the predicted mortalities by using the POSSUM, p-POSSUM, and cr-POSSUM formulas and compared this with the observed ones.

The data in this series were collected retrospectively, which could be criticized and can lead to an amount of missing data. However, because all the necessary physiologic information is available from a routine preoperative assessment and the operative data likewise are covered in the operation notes, retrospective collection of the POSSUM score is reliable.

Tekkis *et al.*[3] proved this already. They found 99.5% of the data; missing data were given the minimum score of one, which left the statistical calculations unaffected. The same was found by Senagore *et al.*,[8] who replaced the 4% missing values by, respectively, a value of zero, an initial post-operative value when available, an average value of the data at a given institute, or a value of 1. None of the strategies degraded the adequacy of the risk assessment with any of the POSSUM variations. (Possum, p-POSSUM, and cr-POSSUM). In our series, 96.3% of the values were found and missing data were replaced by the average of the found data per type of operation indication, which left the statistical calculations unaffected.

Patients with a carcinoma in our series were significantly older and had significantly higher PS and OSS scores, but their observed mortality, although not significant, was lower than in the diverticulitis group even though the same operative procedures by the same group of surgeons were performed. In contrast, the various POSSUM score-predicted mortalities were higher in the carcinoma group. This suggests that diverticular disease, much more than carcinoma, is a strong factor leading to a higher operative risk in this patient group.

In our series, the POSSUM formula overpredicted mortality in all groups while the p-POSSUM equilibration slightly overpredicted mortality in the carcinoma group, slightly underpredicted mortality in the diverticulitis group, and almost matched the overall mortality. Almost exactly the same figures were found with the cr-POSSUM method.

When in the OSS the score for malignancy was replaced by the lowest one, such as the one for diverticulitis, we found that the p-POSSUM as well as the cr-POSSUM score provided the best choice for analyzing mortality rates in elective sigmoid resection for carcinoma or complicated diverticulitis.

CONCLUSION

In conclusion, we found that in this subgroup analysis both the p-POSSUM and cr-POSSUM score accurately predicted the observed overall mortality in patients who underwent elective resection of the sigmoid colon for carcinoma or diverticular disease especially when used without a score for malignancy.

Table 1 Types and numbers of acute and elective colorectal operations from 1990 to 2002

Type of operation	No.	Male	Female	Mortality (%)	Morbidity (%)
Right hemicolectomy	229	98	131	6.1	41.0
Left hemicolectomy	59	33	26	5.1	54.2
Resection sigmoid	316	130	186	5.1	50.6
Anterior resection	117	57	60	6.8	56.4
Anterior resection TME	50	32	18	8.0	58.0
Colostomy after laparotomy	97	36	61	18.6	58.8
Hartmann procedure	225	108	117	20.9	67.6
Colostomy	28	13	15	21.4	50.0
Extended right hemicolectomy	9	4	5	11.1	66.7
Extended left hemicolectomy	9	4	5	0.0	44.4
Resection colon transversum	28	14	14	0.0	53.6
Rectum amputation	66	43	23	4.5	75.8
Resection flexura hepatica	1	0	1	0.0	0.0
Resection flexura lienalis	3	3	0	0.0	66.7
Ileocecal resection	87	37	50	6.9	33.3
Miscellaneous	34	18	16	17.6	52.9
Restore Hartmann	107	57	50	2.8	42.1
Restore loop colostomy	64	31	33	1.6	29.7
Enteroenterostomy	29	16	13	24.1	58.6
Correction colostomy	35	18	17	0.0	17.1
Sub or total colectomy	5	3	2	40.0	80.0
Wedge resection	6	3	3	16.7	50.0
Total	1604	758	846	9.1	50.3

Table 2 Physiologic Score POSSUM (PS)

Score	1	2	4	8
Age (years)	≤60	61-70	≥71	
Cardiac signs	No failure	Diuretic, digoxin, antianginal or hypertensive therapy	Peripheral edema; warfarin therapy	Raised jugular venous pressure
Chest radiograph			Borderline cardiomegaly	Cardiomegaly
Respiratory signs	No dyspnea	Dyspnea on exertion	Limiting dyspnea (one flight) moderate COAD	Dyspnea at rest (rate ≥ 30/min)
Chest radiograph		Mild COAD		Fibrosis or consolidation
Blood pressure mm Hg (systolic)	110-130	131-170 100-109	≥171 90-99	≤89
Pulse (beats/min)	50-80	81-100 40-49	101-120	≥121 ≤39
Glasgow coma score	15	12-14	9-11	≤ 8
Hemoglobin (g/100 mL)	13-16	11.5-12.9 16.1-17.0	10.0-11.4 17.1-18.0	≤9.9 ≥ 18.1
White cell count (x1012/L	4-10	10.1-20.0 3.1-4.0	≥20.1 ≤3.0	
Urea (mmol/L)	≤7.5	7.6-10.0	10.1-15.0	≥15.1
Sodium (mmol/L)	≥136	131-135	126-130	≤125
Potassium (mmol/L)	3.5-5.0	3.2-3.4 5.1-5.3	2.9-3.1 5.4-5.9	≤2.8 ≥6.0
Electrocardiogram	Normal		Atrial fibrillation (rate 60-90)	Any other abnormal rhythm or ≥5 ectopics/min, Q waves or ST/T wave changes

COAD = chronic obstructive airways disease

Table 3 Operative Severity Score POSSUM (OSS)

Score	1	2	4	8
Operative severity	Minor	Moderate	Major	Major+
Multiple procedures	1		2	>2
Total blood loss (mL)	≤100	101-500	501-999	≥1000
Peritoneal soiling	None	Minor (serous fluid)	Local pus	Free bowel content, pus or blood
Presence of malignancy	None	Primary only	Nodal metastasis	Distant metastasis
Mode of surgery	Elective		Emergent resuscitation of ≥2 h possible. Operation <24 h after admission	Emergent (immediate surgery <2 h needed)

Table 4 The colorectal POSSUM scoring system (cr-POSSUM)

score	1	2	3	4	8
Physiological Score (cr-PS)					
Age group (years)	≤60		61-70	71-80	♬ 81
Cardiac failure	None or mild	Moderate	Severe		
Systolic blood pressure (mm Hg)	100-170	>170 or 90-99	<90		
Pulse (beats/min)	40-100	101-120	>120 or <40		
Urea (mmol/L)	≤10	10.1-15.0	>15.0		
Hemoglobin (g/100 mL)	13-16	10-12.9 or 16.1-18	<10 or >18		
Operative Severity Score (cr-OSS)					
Operative severity	Minor		Intermediate	Major	Complex major
Peritoneal soiling	None or serous fluid	Local pus	Free puss or faeces		
Operative urgency	Elective	Dukes' C	Urgent		Emergency
Cancer staging	No cancer or Dukes' A-B		Dukes'D		

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Table 5 Regression equations in POSSUM, cr-POSSUM, and p-POSSUM scoring systems

POSSUM-mortality
$\mathrm{Ln}[P/(1\text{-}P)] = -7.04 + (0.13 \quad PS) + (0.16 \quad OSS)$

POSSUM-morbidity
$\mathrm{Ln}[P/(1\text{-}P)] = -5.91 + (0.16 \quad PS) + (0.19 \quad OSS)$

p-POSSUM-mortality
$\mathrm{Ln}[P/(1\text{-}P)] = -9.065 + (0.1692 \quad PS) + (0.1550 \quad OSS)$

cr-POSSUM-mortality
$\mathrm{Ln}[P/(1\text{-}P)] = -9.167 + (0.338 \quad cr\text{-}PS) + (0.308 \quad cr\text{-}OSS)$

P = risk of mortality or morbidity; PS = physiologic score; OSS = operative severity score

Table 6 Type of post-operative complications

1. Deep wound infection: lay open of the wound was mandatory
2. Intra-abdominal abscess: confirmed by laparotomy or percutaneous drainage
3. Anastomotic leak: confirmed by intraluminal contrast studies and/or laparotomy
4. Bleeding or significant wound haematoma
5. Pulmonary: confirmed by chest x-ray and/or mucus cultures
6. Thrombosis and/or pulmonary emboli: confirmed by either venography, duplex ultrasonography and/or ventilation/perfusion scans
7. Pressure ulcers
8. Urinary tract: infections confirmed by urine cultures
9. Cardiac: confirmed by electrocardiography and/or CK/CKMB studies or by chest x-ray
10. Central nervous system: confirmed by computed tomographic scan
11. Sepsis: confirmed by blood cultures
12. Miscellaneous
13. Multiple organ failure

Table 7 Type of extra primary operation

	N=
Splenectomy	1
Resection small intestine	4
Formation colostomy	4
Suturing perforated intestines	1
Cholecystectomy	1
Inguinal hernia	2
Incisional hernia	2
Ureteral lesion	1
Partial bladder resection	20
Uterus or adnex resection	8
Debulking	1
Partial resection abdominal wall	1

Table 8 Comparison between the carcinoma and the diverticulitis group

	Carcinoma N = 120	Diverticular disease N = 121	*P*
Gender m/f	64/56	44/77	0.008
Mortality	1.7%	3.3%	0.685
Morbidity	43.3%	52.1%	0.175
Age	68.1 yrs	63.8 yrs	0.002
PS	18.3	16.7	0.015
OSS	13.8	11.5	<0.001
cr-PS	9.4	8.5	<0.001
cr-OSS	7.7	7.0	0.004
>1 primary operation	16.7%	23.1%	0.208
Secondary operations	8.3%	10.7%	0.524
Covering loop colostomy	4.1%	0.8%	0.213

Table 9 Post-operative complications

Type of complication	Carcinoma N = 120 (%)	Diverticular disease N = 121 (%)	*P*
Wound infection	5.8	11.6	0.114
Intra-abdominal abscess	2.5	4.1	0.722
Anastomotic leak	3.3	7.4	0.254
Bleeding/haematoma	1.7	4.1	0.446
Pulmonary infection	5.0	8.3	0.439
Thromboembolic	1.7	3.3	0.684
Pressure sores	0	0.8	1.000
Urinary tract	30.8	38.0	0.241
Cardiac	2.5	5.8	0.333
Sepsis	0.8	5.0	0.120
Miscellaneous	12.5	9.9	0.525
Multiple organ failure	0.8	0	0.498

Table 10 Observed:Expected (O:E) death ratios, the score for carcinoma included

	O:E ratio POSSUM	O:E ratio p-POSSUM	O:E ratio cr-POSSUM
Carcinoma	0.16	0.45	0.45
Diverticulitis	0.52	1.50	1.43
Total	0.30	0.83	0.83

Table 11 Observed:Expected (O:E) death ratios;
the score for carcinoma replaced by the minimum score of 1

	O:E ratio POSSUM	O:E ratio p-POSSUM	O:E ratio cr-POSSUM
Carcinoma	0.23	0.63	0.55
Diverticulitis	0.52	1.50	1.43
Total	0.37	1.04	0.93

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Chapter 6

Nationwide decline in annual numbers of abdomino-perineal resections: effect of a successful national trial?

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ABSTRACT

Objective

Large national trials may influ-ence surgical practice. In this study the relation between the successful national randomized trial on the management of rectal cancer (the Dutch TME trial) and national ratio of abdomino-perineal resection to low anterior resection and anastomosis was analysed.

Patients and methods

In the study period, 1994–99, 15978 patients underwent either abdomino-perineal resection (n = 2575) or low anterior resection and anastomosis (n = 13403). The Dutch TME trial started in 1996 and a total of 1530 patients were included by 83 hospitals and 82.1% of these patients were treated from 1997 to 1999. Teaching sessions, tutor assisted surgery and quality control formed an integral and important part of the TME trial.

Results

Ratio of abdomino-perineal resection *vs.* low anterior resection was compared between period I (1994–96) and period II (1997–99). The ratio decreased from 0.19 to 0.13 between periods I and II (95% CI, - 0.08 to -0.04, $P< 0.001$). In-hospital mortality rate did not change between period I and II (3.5% *vs.* 3.7%, 95% CI - 0.08 to- 0.03, $P= 0.385$).

Conclusion

Significant changes in surgical attitude may accompany successful national randomized trials in which investigated surgical procedures are specified, taught, and controlled. The APR ratio declined by 32% in The Netherlands during and following the Dutch TME trial, without a rise in hospital mortality rate for rectal resections.

INTRODUCTION

It has been suggested that surgeons lack adequate knowledge of the literature[1]. This has sometimes led to inappropriately rapid changes in surgical practice. Subsequently unfavourable results have been obtained in the learning period of new procedures [2-4] although some problems maybe technique-rather than experience- related [5]. When new protocols are introduced in combination with training programs that focus on the quality of the investigated surgical technique favourable results may be obtained in a short period [6]. One such trial, introducing a new surgical technique, was started in The Netherlands in January 1996. This was the so called Dutch TME trial, which compared the effect of total mesorectal excision (TME) alone *vs*. TME surgery after a short course of pre-operative radiotherapy (randomized) for local control of rectal cancer [7]. The surgical approach to rectal cancer may change when surgeons participate in a trial [6] and adherence to a protocol may change the clinical outcome of colorectal surgery [8].
The aim of this population-based study was to define nation-wide changes in surgical practice regarding the use of abdomino-perineal resection and low anterior resection. A further aim was to determine whether changes in surgical practice would affect post-operative hospital mortality rates for abdomino-perineal resection and low anterior resection.

PATIENTS AND METHODS

DATA

In The Netherlands, independent hospital based medical registration departments collect a set of data after discharge or death of a hospitalized patient. This datasheet is extracted from the clinical notes, a compulsory discharge letter by the responsible consultant or his assistant, and compulsory notes of the operation. The completeness of the dataset is guaranteed because datasets with incomplete or blank compulsory data fields are not accepted or processed by the software in use. Patient's notes cannot go to the hospital archives without the dataset being complete. The completed compulsory dataset is sent to the Dutch National Medical Registry (Prismant, Utrecht, The Netherlands) and further processed.

COMPULSORY DATA FIELDS USED IN THIS STUDY

Sex.

Age.

Hospitalization. Number of days in hospital.

Type of operation. Coding for type of operation was based on the 'International classification of diseases, 9th revision clinical modification'. Abdomino-perineal resection (APR), Dutch code 5484. Other rectal resections (RR), Dutch code 5485. Local rectal resection, pull through operations, and rectal surgery as part of a total colectomy were excluded.

Discharge or death. Discharge alive (home, elderly home, other hospital) or death in hospital (from whatever cause but during an admission for primary rectal surgery).

Hospital number. Anonymous number per hospital created by the Dutch National Medical Registry (Prismant) and unknown to the research group. Hospital anonimity could only be lifted by written request of the Department of Surgery of that specific hospital.

Type of hospital. University hospital (A), peripheral hospital with training facilities (B), peripheral hospital without training facilities (C). Type of hospital was based on the classification of hospitals by the Dutch Society for General Surgery as per 1999.

Year of surgery. From 1994 through to 1999.

DATASET, DEFINITIONS, AND STATISTICAL ANALYSIS

Data were retrieved and delivered in SPSS format. Statistical analysis was done with SPSS software (statistical product and software solutions 10.0 for windows, SPSS inc., Chicago, Illinois, USA). Both descriptive statistics, ^{2} test, one-way analysis of variance, and paired samples t-test were used. APR ratio was defined as number of APR's divided by number of all rectal resections (APR and RR). ??

CHOICE OF PERIODS

The Dutch TME trial was started in January 1996 and patient accrual was well underway in 1997. The inclusion of patients ended in January 2000. Patients included in the TME trial, and total numbers of rectal resections (APR plus RR) is given in Table 1. A total of 1530 Dutch patients were included in the trial and 1488 (97.3%) underwent TME surgery with curative intent. Because only 17.5% of patients had been included by the end of 1996 if was felt that the influence, if any, of the TME trial would be visible from 1997 onwards. Two equal periods of sufficient length were therefore created: period I included patients operated in 1994–1996 and period II included patients operated in 1997–1999.

inclusion criteria and consequences

Hospitals were included if rectal surgery had been performed in all 6 years of the study period. Data were retrieved from 127 hospitals, and these represent 98.4% of all hospitals in The Netherlands where elective rectal resectional surgery is performed. Of these 19 did not fulfill the inclusion criteria because of mergers or closing down of hospital during the study period (n = 12), starting as a new hospital but not for the full length of the study period (n = 5), or coding discrepancies (n = 2), leaving a group of 108 hospitals that were included in the study. These 108 hospitals comprised 7 university hospitals (group A), 34 peripheral hospitals with training facilities (group B), and 67 nontraining peripheral hospitals (group C). Only adult patients undergoing elective surgery were included.

dutch TME trial, instruction courses

The design of the Dutch TME trial has been previously published. Quality control of the TME trial was assured through an extensive structure of workshops, symposia, and instruction videos. In addition a monitoring committee of 23 specially trained instructor surgeons was formed for on-site instructions. The first five TME's had to be supervised by these instructor surgeons.

results

There were no differences in age and sex of patients between periods II and I. Patients in Group A hospitals were significantly younger than in Groups B and C hospitals (56.6 years *vs.* 64.9 years, 95% CI of difference, -9.5 to -7.5, $P < 0.001$). From 1994 to 1999 a total of 15978 rectal operations were performed of which 2575 were APR's and 13403 were RR's. Between period I and period II, the APR ratio decreased from 0.19 to 0.13 in the total group which amounts to a decrease of 399 APR's being performed in period II. Between period I and period II ratios of APR to total resectional rectal surgery (APR plus RR) declined significantly and in equal measure in Groups B and C but not in Group A hospitals (Table 2).
Patient inclusion for the Dutch TME trial is shown in Fig. 1. Decline of APR's over the years is also shown in Fig. 1. Of all TME procedures 36% were assisted by a TME trial instructor. In the first quarter of the TME trial 89% of TME procedures

were instructor assisted, and in the last quarter 26% TME procedures were instructor assisted. Of 108 hospitals included in this study ultimately 84 (78%) also included patients in the TME trial.
Hospital mortality rates for rectal resections (APR plus RR) were 3.5% for period I and 3.7% for period II and mortality rates did not change significantly between period I and II for either hospital group (Table 3). There was no difference between hospital categories regarding discharge-policies. All hospital categories discharged equal percentages of patients to other hospitals (One way ANOVA, d.f. 2, F= 0.893, P= 0.41). There was a significant decline in mean hospital stay between period I and period II (21.6 *vs.* 20.5 days, 95% CI of difference 0.64–1.4, P< 0.001). Between period I and period II the number of rectal operations per surgeon increased from 6.6 to 8.5.

Discussion

This population-based study has shown that significant national changes in surgical attitude towards the use of abdomino-perineal resection have developed in a relative short period. This study has also shown that these changes had no negative effect on hospitality rates.
Since the mid-eighties all hospitals in The Netherlands are obliged to collect a standard dataset on discharge or death of a patient. Hospitals are also obliged to send this dataset to the Dutch National Medical Registry.
Although the transport of data is now via the electronic highway the process of collecting data is by and large unchanged. This database has been used to define surgical outcome of a specific surgical procedure on a national basis [9,10]. The Dutch National Medical Registry has recently embarked on a national study to define reliability of the data management process. A comparison of an independent prospective database collected by a surgical firm in one hospital with matched data from the Dutch National Medical Registry showed equal mortality rates [11].
The interest in TME surgery has increased over the past 10–15 years. In 1990 the TME concept was mentioned in less than 10 articles but in 1999 it appeared in well over 100 publications. TME is a regular feature at almost all colorectal symposia, and TME has been the subject of national and international congresses. It is also of interest that TME training has been very important in those countries that organized prospective TME studies. For example hospitals that participated in the Dutch TME trial accepted instructors, who were mostly academic surgeons, to assist during the first TME procedures. A recent Swedish study has shown that APR ratios may decline in a limited region when surgery for rectal cancer is performed by less but better trained surgeons [6]. Similar results are now available on a national basis. The national decline in total number of APR's

coincided with the successful Dutch TME trial. Quality management was a very important and successful aspect of the TME trial. This is reflected in the large number of instructor assisted TME's. A randomized trial that clearly defines quality of surgical therapy and how it should be achieved is bound to have a profound effect on surgical attitude when almost 65% of all national hospitals contribute patients to such a trial. The most likely explanation is improved awareness, probably through training and specialization. Most surgeons working in hospitals in The Netherlands are part of a firm, in which all partners (consultant level) are supposed to be equal, in terms of financial compensation and workload.

The Dutch TME trial, and also work by others [12], has made surgeons aware that probably not all surgeons in a firm should perform TME procedures, or other rectal surgery. Although this has not been laid down in consensus statement compliance among surgeons has been impressive. This has led to an almost overnight differentiation. Effects of differentiation are also reflected in the increased number of rectal operations per surgeon, the significant decline in APR ratio, the decline of mean hospital stay after rectal resections [13] and ultimately the low percentage of local recurrences achieved in both patient-groups of the TME trial [14].

TME instructors were mostly academic surgeons and changes in surgical attitude in academia may have preceded changes in peripheral hospitals. It is also possible that a number of patients were transferred to academic units when an APR was needed. Both factors may have contributed to the steady numbers of APR's in academic units during the study.

This population-based study can only describe changes in surgical practice and its consequences regarding hospital mortality of rectal surgery. Lower mortality rates in group A hospitals are partly explained by age differences of patient group [15]. The final morbidity and mortality analysis of the Dutch TME trial showed a slight increase in post-operative morbidity but not in post-operative mortality in those patients randomized to receive pre-operative radiotherapy [16]. The effect of pre-operative radiotherapy would have been diluted anyway because only a minority of patients, even in the second half of our study, received pre-operative radiotherapy. It is also reassuring that the increase in coloanal and low rectal anastomosis has not led to an increase in overall hospital mortality. Functional outcome after colo-anal or low rectal anastomosis is not always excellent and may reduce quality of life [17]. Also anastomotic leaks occur not infrequently after TME with ultralow anastomosis [18] and functional results are poor even if the anastomotic leak can be dealt with conservatively [19,20]. The decline in number of APR's performed for low rectal cancer may continue for some time. It is by no means certain that a permanent colostomy is never the right choice for individual patients, even if by oncological standards resection and anastomosis would be feasible. Variability in delivery of cancer care [21,22] may be expressed by the large inter-hospital and inter-surgeon variation in local recurrences after surgery for rectal cancer [23–25]. The Dutch TME trial has shown that the introduction of a standardized technique may drastically reduce this complication. A by-product of the teaching sessions, that were an integral part of the Dutch TME trial, was that the state of the art in rectal cancer surgery was taught more effectively to participating surgeons. As the larger part of hospitals in The Netherlands contributed patients to the TME trial this translated into the diminished nation-wide number of APR's performed.

Table 1 TME trial inclusion as part of total number of rectal resections per annum

Year	Total rectal resections	Annual no. APR	TME trial inclusion	TME trial inclusion as a % of rectal resections
1994	2466	492	-	0
1995	2564	505	-	0
1996	2631	490	274	10.4
1997	2789	492	482	17.3
1998	2681	296	456	17.0
1999	2847	300	318	11.2
Total	15978	2575	1530	9.6

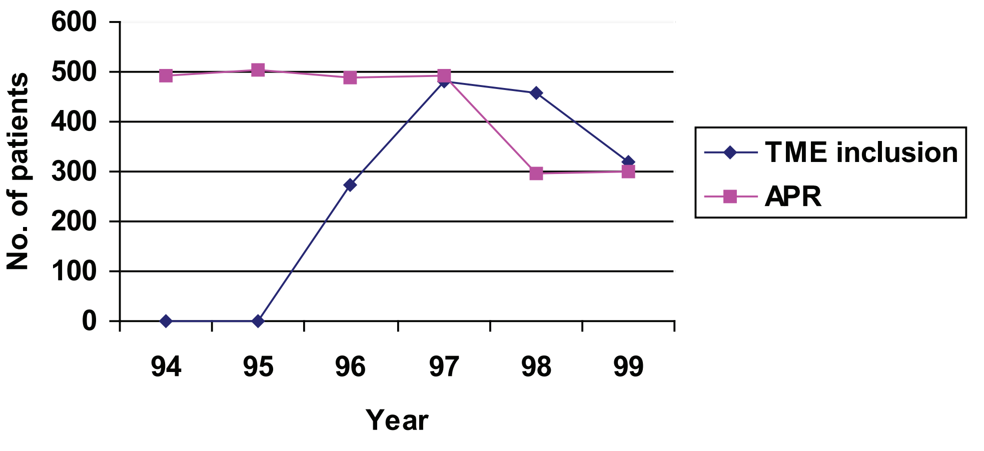
Table 2 APR ratio

	n	APR ratio Period I	APR ratio Period II	95% CI of difference	*P*-value
Group A	7	0.20±0.1	0.20 ±0.1	-01, 0.1	0.974
Group B	34	0.22±0.1	0.14 ±0.1	-0.1, -0.05	<0.001
Group C	67	0.17±0.1	0.12 ±0.1	-0.08, -0.03	<0.001
Total	108	0.19±0.1	0.13 ±0.1	-0.08, -0.04	<0.001

Table 3 Mortality rates of rectal resection (APR plus RR)

	n	Period I	Period II	95% CI of difference	*P*-value
Group A	7	2.8 $\pm$0.2	1.8 $\pm$0.1	-0.1, 0.3	0.205
Group B	34	3.4 $\pm$0.2	4.0 $\pm$0.2	-0.15, 0.03	0.205
Group C	67	3.6 $\pm$0.2	3.8 $\pm$0.2	-0.1, 0.06	0.638
Total	108	3.5 $\pm$0.2	3.7$\pm$0.2	-0.08, 0.03	0.385

Fig. 1 TME inclusion versus APR numbers over the period 1994-1999



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chapter 7

Operative mortality after colorectal resection in The Netherlands

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ABSTRACT

Background: The aim of this study was to quantify factors related to operative mortality after colorectal resection in The Netherlands.

Method: Multilevel logistic regression modeling was used. Institutional effects were calculated with and without adjustment for specific patient (age, sex, urgency of operation) and hospital (number of procedures, type of hospital) characteristics. All adult Dutch patients who underwent primary colorectal resection between 1994 and 1999 were included, except those who had (sub-) total colectomy or local rectal resection.

Results: A total of 67594 patients underwent colorectal resection. The in-hospital mortality rate was 7.0 per cent (elective 3.9 per cent, acute 14.3 per cent). Acute operation (odds ratio 3.89) and age (odds ratios 2.63, 5.23 and 10.17 for patients aged 50-69, 70-79 and 80 or more years respectively compared with those aged less than 50 years) had the strongest effects, followed by male sex (odds ratio 1.48) and type of hospital. There was no difference in operative mortality rate between low-, medium- and high-volume hospitals.

Conclusion: In The Netherlands, advanced age and acute operation are by far the most important factors related to operative mortality after colorectal resection. Male sex and type of hospital have only a modest effect, and there is no discernable effect of hospital volume.

INTRODUCTION

Colorectal resection forms a large part of the general surgical workload in The Netherlands. The need for outcome studies is increasing because of the increasing cost of health care and the role of funding agencies in the financing and distribution of health care. Accurate information is needed to guide long-term decisions regarding the structure and control of health care systems. The outcome of surgery may be one of the reasons underlying a change in healthcare distribution. In the USA outcome of surgery, mainly measured as the operative mortality related to both hospital and surgeon experience in certain procedures, has become an important but also controversial subject. A volume-outcome relation for some complex surgical procedures may exist, but conflicting studies have also been presented [1,2]. Some of the evidence that dates from the 1980s and 1990s is flawed because appropriate statistical analyses were not used [3]. In earlier studies no statistical allowance was made for the clustering of patients within one hospital.
To allow for clustering of patients with shared characteristics in one hospital multilevel logistic regression (MLR) modelling may be used. This is a relatively new technique that has been used to analyze pupil performance in a school system and patient outcome in a healthcare system [4-7].
The aim of this study was to quantify factors related to operative mortality after colorectal resection in The Netherlands using MLR modelling

PATIENTS AND METHODS

In The Netherlands, independent hospital-based medical registration departments collect a set of data after discharge or death of a hospitalised patient. Data sets with incomplete fields are not processed and cannot be filed. The complete data set is sent to the Dutch National Medical Registry (Prismant, Utrecht, The Netherlands).
All adult patients who underwent primary operations involving resection of the colon or rectum between 1994 and 199 were included in this study, with the exception of those who had local rectal resection, pull through operations, or (sub) total colectomy. Acute surgery was defined as surgery taking place within 24 hours after an acute admission. All other surgery was classified as elective. Operations were coded according the International Classification of Diseases (9th revision, clinical modification). Operative mortality was defined as death from any cause during the primary hospital admission. Teaching hospitals offered a part (3- 4 years) of the 6-year curriculum of surgical training in The Netherlands.

Teaching status was granted by the Dutch specialist registry. General hospitals had no teaching facilities for surgical residents and consequently general surgeons performed all colorectal resections in these hospitals. Hospitals were categorized according to the numbers of patients treated in the 6-year period; low-volume (1-540 patients), intermediate-volume (541-773 patients) and high-volume (more than 773 patients) hospitals were defined. Sixty-nine low-volume hospitals treated 22285 patients, 36 intermediate-volume hospitals treated 22894 patients and 23 high-volume hospitals treated 22415 patients.

STATISTICAL ANALYSIS

Logistic regression analyses were carried out with death (yes/no) as the response variable and the categorical variables type of hospital (university, teaching or general), total number of procedures per hospital (low, intermediate or high), urgency of surgery (acute or elective), sex and age (20-49, 50-69, 70-79 or 80 or more years) as independent variables. In the logistic regression models each categorical independent variable was represented by a set of dummy variables with one of the categories as the reference category. Because patients in the same hospital share many unmeasured characteristics, such as staff and financial resources, it can be expected that the outcome data of patients in the same hospital will correlate. To account for this intrahospital correlation, a multilevel analysis is appropriate. In statistical parlance, the patients are the level 1 or micro-units and the hospitals are the level 2 or macro-units. Of the independent variables, type and size of hospital are level 2 or institutional variables, and urgency of surgery, sex and age are level 1 or individual variables. Several multilevel logistic regression models were fitted to the data. Firstly, the empty model that is the model without independent variables was fitted. This model serves as a baseline. Next, the model with main effects only was fitted. Finally the model with all first-order interactions between two independent factors was fitted. Examples of first-order interactions were hospital status and urgency of operation, hospital volume and age of the patient, age and sex of patients. For each model, differences between hospitals can be characterized by the predicted level 2 (hospital) effects measured on a logit scale. These may be used for the ranking of hospital performance and for comparisons between hospitals [8]. Zero on a logit-scale represents average performance. Hospitals that perform better than average will have a negative logit and those that perform below average have a positive logit. This approach is analogous to assessing school performances with MLR modelling[4]. All multilevel analyses were carried out with the program MLwiN 1.1 according to recently described methods [9-12].

RESULTS

Between 1994 and 1999 a total of 67594 patients had a colorectal resection, 32475 men (48.0 per cent) and 35119 women (52.0 per cent). Mean age was 69.2 years. Some 5816 operations were performed in eight university hospitals, 28155 operations in 37 teaching hospitals and 33623 operations in 83 general hospitals. Operations comprised 48240 partial colectomies (71.4 per cent) and 19354 rectal resections (28.6 per cent). There were 19981 (29.6 per cent) acute and 47613 (70.4 per cent) elective procedures.

The overall in-hospital mortality rate was 7.0 per cent, 3.9 per cent after elective procedures and 14.3 per cent after acute operations. The relation between age, mode of surgery and post-operative mortality is shown in *Table 1*. Patients aged over 70 years comprised 46.9 per cent of the total group but accounted for 76.0 per cent of operative deaths. The relationship between hospital volume and outcome is shown in *Table 2*. The mean age and ratio of acute to elective operations was the same in all hospital-volume groups. The mean crude operative mortality rate was lowest in the low-volume hospitals.

The empty multilevel model showed a small variance in mortality between hospitals ((0.065; (95 per cent confidence interval (CI) = 0.038 to 0.091)), and thus a small intrahospital correlation (0.019). The results of adding the five independent variables to the empty multilevel model are shown in *Table3*. In this model the effect of each separate independent variable is calculated. Acute nature of an operation (odds ratio=3.89) and age (odds ratios 2.63, 5.23, and 10.17 for patients aged 50-69, 70-79 and 80 or more years respectively compared with those aged les than 50 years) had the strongest effects. The odds of death roughly doubled with each succeeding age category. Teaching hospitals and general hospitals performed better than the university hospitals. When the contribution of each independent factor was determined, age and urgency of surgery were by far the most important independent factors. For example, age was more important than hospital volume by a factor of almost 400 (*Table 4*). When low-volume hospitals were analyzed separately, no relationship between volume and performance was found (*P=0.290*). In the main-effects only model, 12 hospitals performed significantly worse than the average hospital and three performed better. Adding all interactions to the main-effects model improved the model significantly. In the model that included all interactions, nine hospitals performed significantly worse than the average hospital and two performed better. This is illustrated by the fact that for these hospitals the 95 per cent c.i. of the specific hospital effect did not cross the zero-line (*Figure 1*).

The rank order of the hospitals based on the main-effects model and the model containing all interactions coincided very well (Spearman's = 0.964). ?? The Spearman rank correlation between crude mortality rank and the model containing all interactions was 0.727. When rank based on crude operative mortality rates and rank based on the model containing all interactions were compared, hospitals could end up 72 places higher and up to 61 places lower (*Figure 2*). Over 60 per cent of hospitals changed rank by more than ten places and 40 per cent of hospitals changed rank by more than 25 places.

DISCUSSION

This study has shown that there is little hospital variation in mortality rate after colorectal resections in The Netherlands. Advanced age and acute mode of surgery are the most important factors related to post-operative mortality after colorectal resections. Less important independent factors are male sex and teaching status of hospitals. Hospital volume is not a predictor of post-operative mortality.

Ranking of hospitals is becoming more important and long-term decisions are sometimes based on profiles derived from crude databases. These profiles may not reflect the true nature of interhospital differences, even after correction by multivariate regression modelling. MLR modelling has been used to rank acute cardiac care units, and large differences in hospital ranking were shown to exist when ranking orders were based solely on crude mortality rates and not on adjusted hospital effects calculated by MLR analysis [5]. This effect was also seen in a study of 87,078 major non-cardiac operations, which showed a rank-order correlation between crude mortality ranking and adjusted rank order of 0.64, and that 93 per cent of hospitals changed rank after risk-adjustment [13]. This effect was also observed in the present study. Ranking of hospitals should not therefore be based on crude in-hospital mortality rates after colorectal resection.

In the first-order interaction MLR model, 7 per cent of hospitals significantly underperformed and hospital variation accounted for very little unexplained variation. The Dutch system of hospital-based delivery of colorectal care seems well balanced. This does not necessarily mean that it is good. The present national data can only be compared with international non-selected data of equal completeness. Three recent studies have shown mortality rates of 6.7-7.5 per cent for unselected colorectal resections [14-16]. These results compare well with the in-hospital mortality rate of 7.0 per cent of the present study. On the other hand, many studies, often on selected groups of patients, report lower figures on in-hospital mortality rates. It is very difficult, if not impossible, to draw conclusions from these data, not in the least because international and national differences in the organization of healthcare systems exist and conclusions reached in one nation may simply not translate to another nation. In a recent study the

differences in post-operative mortality for non-cardiac surgery were compared between academic units in the UK and the USA [17]. Only minor differences in risk stratification of patients were found but these could not account for a fourfold increase in post-operative mortality in the UK. Unstudied variables in structure, process and outcome of care apparently exist between nations.
The validity of the data collection has been the subject of a large national study performed by the Dutch Central Data Registry (Prismant). Good correlation was found between the administrative data and feedback obtained from the treating surgeon, especially for patients who underwent a surgical procedure. A correct administrative coding was obtained in over 95 per cent of patients [18]. In authors' own institution there was complete agreement between mortality figures and only 0.4 per cent difference in the number of colorectal resections performed.
The administrative data set used in the present study has certain limitations. These mainly relate to limited information with regard to the preoperative health status. The model used by Khuri *et al.* [2] relied on clinical data collected by specially trained nurses showed good discrimination, and failed to show a volume-outcome effect following colectomy. Studies that have relied on clinical data rather than administrative data have shown less obvious volume-outcome effects [3]. The present model could be improved if national data that allowed stratification of patient-related risk factors were included. The American Society of Anesthesiologist classification is not suitable for this purpose and other methods, such as the Physiologic and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) or p-POSSUM scoring system, may be more appropriate [19]. The present model identified nine hospitals that underperformed but more research is needed to determine the level of information required to determine why.
The results of the present study contradict recent data from the USA that have shown an inverse relationship between volume, both related to surgeon and hospital [20-22]. The Leapfrog initiative, started by a group of health care purchasers in the USA, has lent much credibility to the volume effect in the USA. However the conclusions reached by Birkmeyer *et al.* [23] on the potential benefits of the Leapfrog initiative were criticized by the executive director of the American College of Surgery at the time, who stated that the conclusions were based on extrapolated data collected from an extremely heterogeneous volume-outcomes literature. Patient selection was present and no data on individual surgeon performance were given [24]. In a later study it was stated that an inverse relationship between hospital volume and in-hospital mortality existed for many surgical procedures. The *C* statistic for the model used in this study was at most 0.71 (for prostatectomy), but could be as low as 0.61 (for pneumonectomy),

giving the model used only intermediate discriminatory power [1]. The Society of University Surgeons also did not concur, mainly because it remained unclear what the impact of regionalization, or volume shifting, on mortality and quality of surgical care would be [25]. A recent survey collected all published data on volume-outcome relationships from 1983 to 2000 and found 12 studies relating to colorectal surgery [3]. A significant absolute median difference of 1.9 in mortality in favor of high volume hospitals (median of 115 procedures a year) was found. However in eight of 12 studies no relationship was found and it was noted that multivariate analysis was used in the minority of studies. The largest single USA healthcare provider launched a study on the volume effect in their 123 Veterans Affairs' surgical departments but found no correlation between hospital volume and 30-day mortality rate after colorectal surgery [2]. This study was criticized because some surgeons worked in more than one hospital and hospitals were at best medium volume. In another study from the USA, using nationwide data, it was noted that both surgeon and hospital volume had very small, although significant, effects in the prediction of mortality after colorectal resection [26]. For example the effect contributed by an emergent operation was 34 times larger than the effect of a large-volume hospital. The authors, however, concluded that volume remained an acutely mutable variable with a significant effect on mortality and, as such, deserved its place in the rationalization debate.
The volume-outcome discussion related to operative mortality after colorectal surgery in Dutch hospitals may well be not an issue because of the way The Netherlands has organized colorectal care. An average of 88 colorectal resections per hospital was performed yearly in The Netherlands. This would place Dutch hospitals on average in the high-volume category in most studies emanating from the USA.[1, 20, 21, 26-28]. However, other outcome variables may also be important. It has been shown recently that high-volume providers have a significantly better long-term outcome for complex cancer surgery[29], although it is unclear whether larger differences in hospital volumes would lead to a different outcome after MLR modelling. It is also uncertain what the minimal volume of colorectal resections per hospital should be. However on the basis of the present data it seems that hospital volume does not have an appreciable impact on operative mortality after colorectal resection in The Netherlands and should not be included in healthcare decisions.

Table 1 Post-operative crude mortality rate as a function of age and urgency of operation

Age (years)	n	Deaths	Mortality (%) Elective	Acute
20-49	18479	356	1.0	4.3
50-69	17392	780	2.5	10.5
70-79	20735	1409	5.0	17.5
≥80	10988	2189	10.3	25.4
Total	67594	4734	3.9	14.3

Table 2 Hospital volume, hospital characteristics and mortality

Hospital volume	Mean no. of colorectal resections per year per hospital	Acute: Elective	Mean patient age (years)	Mortality rate (%)		
				Overall	Elective	Acute
Low (*n*=69)	54	0.29	69.9	6.4	3.7	12.9
Intermediate (*n*=36)	106	0.30	69.4	7.3	4.1	14.6
High (*n*=23)	162	0.30	69.0	7.4	4.0	15.5
Total (*n*=128)	88	0.30	69.4	7.0	3.9	14.3

Table 3 Odds ratio for independent factors in the main effects multilevel logistic regression model.

		Odds ratio	
Hospital type	University	1	
	Teaching	0.74	(0.61 - 0.89)
	General	0.62	(0.51 - 0.77)
Hospital volume			
	Low	1.00	
	Intermediate	1.12	(0.96 - 1.3)
	High	1.16	(1.00 – 1.34)
Age (years)			
	20-49	1.00	
	50-69	2.63	(2.33 – 2.98)
	70-79	5.23	(4.63 – 5.91)
	≥80	10.17	(8.96 – 11.55)
Acute operation		3.89	(3.63 – 4.17)
Male sex		1.48	(1.40– 1.57)

Values in parentheses are 95 per cent confidence intervals

Table 4 Weight of independent factors in the main effects multilevel logistic regression model

	Wald 2	D.f.	*P*
Hospital type	20.3	2	<0.001
Hospital volume	3.8	2	0.150
Age	1422.0	3	<0.001
Acute operation	1468.7	1	<0.001
Male sex	177.0	1	<0.001

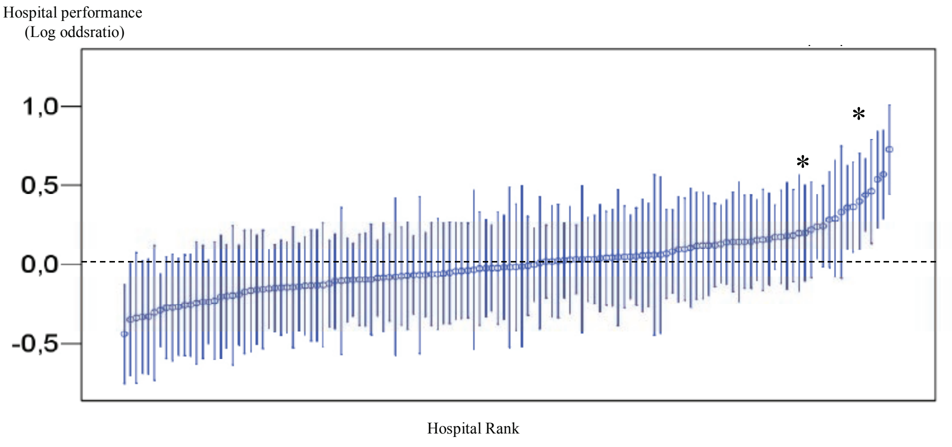

Fig. 1 Hospital performance in the multilevel logistic regression model. Performance is expressed as log odds ratio (95 per cent confidence interval). A negative value signifies better performance than average and a positive value indicates worse performance. Hospitals marked with an asterix underperformed significantly (95 percent confidence interval does not cross zero line)

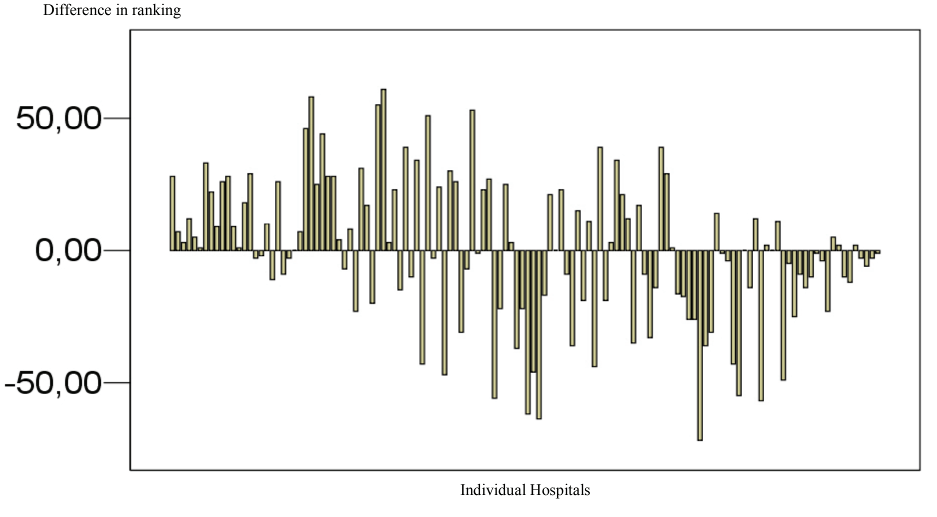

Fig. 2 Difference between crude mortality rank and rank based on multilevel logistic regression (MLR) modelling. A positive value means that, after MLR correction, a hospital performed better than was expected from crude ranking only.

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Chapter 8

SUMMARY AND CONCLUSIONS

In this thesis the outcome of colorectal surgery, performed by the surgical staff of the Zaans Medical Centre, has been analyzed. Crude results of mortality and morbidity after various types of colorectal surgery, performed from 1990-2001, have been presented. Presenting crude results, though useful, can only be descriptive but is not explanatory of mortality and morbidity. Many factors, many as yet unstudied, play a role in the outcome of colorectal surgery. It is only through proper analysis of these factors that risk-stratification of patients is possible. Audit of surgeons and surgical units is only meaningful if outcome is related to risk-stratification of patients. Also outcome studies can only be compared when data on risk- stratification are known.
The purpose of this thesis was to identify risk factors that predict morbidity and mortality after colorectal surgery.

Various methods that have been used in the USA, the UK, and The Netherlands to improve, compare and audit outcome of surgery are discussed in **chapter 1.** The database that is the foundation of most of the studies presented in this thesis is described and validated. It contains a consecutive series of colorectal operations from 1990-2001. The risk-adjustment system used in this thesis is described and the preference for this system is explained. Also the results of applying this system to our database are presented and discussed. The outline of the thesis is stated in the last paragraph of this chapter.

In **chapter 2** the outcome of elective primary surgery for diverticular disease of the sigmoid colon in relation to patient- and disease related factors, using the items of the POSSUM scoring system (Physiologic and Operative Severity Score for the enUmeration of Mortality and morbidity), is discussed. Patients were operated on strict indications according to the guidelines of the American College of Gastroenterology and the American Society of Colon and Rectal Surgeons. Expected morbidity and mortality figures were calculated with the POSSUM equation. The observed mortality data were audited by comparing them with the POSSUM predicted mortality in several mortality risk scales. Factors leading to a higher morbidity or mortality risk were identified. Also peri-operative management failures were investigated in the deceased group of patients. Almost 54% of the patients developed postoperative complications. Type and frequency of complications in relation to gender, and in relation to non-

survivors and survivors are described in detail. Significantly more complications were seen in patients with a higher POSSUM Physiologic Score (PS). Higher POSSUM scores were mainly caused by higher scores for changes in blood pressure, pulse rate and hemoglobin levels. Women suffered more urinary tract infections whereas men had more intra-abdominal abscesses and needed more re-operations for complications. No relation between the Operative Severity POSSUM Score (OSS) and the complication rate was found. Seven of 149 patients died in the hospital for a postoperative mortality rate of 4.7%. Patients who died had higher Physiological POSSUM Scores and Operative Severity POSSUM Scores. Physiologic items that contributed to higher Physiologic Scores in deceased patients were age, pulse rate, haemoglobin, white cell count, urea, sodium and potassium. Operative items that contribute to higher Operative Severity Scores in deceased patients were multiple procedures and amount of blood loss. The observed mortality rate in our series matched the POSSUM predicted mortality in high-risk patients but in low risk patients the POSSUM system overpredicted mortality. Analysis of the perioperative management in deceased patients revealed possible management failures in three patients.
It was concluded that morbidity and mortality after elective surgery for diverticulosis of the sigmoid colon are to a large extent driven by patient- and disease related factors. A risk stratified analysis like the one presented in this chapter may be helpful in understanding the complexity of morbidity and mortality. Only when risk stratification of patients is known, and indications for surgery are properly described can results from surgeons, surgical units or data presented in the literature be compared.

The aims of the study presented in **chapter 3** were to define and describe morbidity and mortality of primary surgery for acute complications of diverticulitis of the sigmoid colon. Also the association between morbidity and mortality, in a group of patients rigorously defined for severity of diverticulitis and patient risk factors was analysed.
Over a twelve year period a consecutive series of 114 patients, suffering from acute complications of diverticulitis of the sigmoid colon, were operated. Indications for operation were perforation peritonitis, colonic obstruction, or failed conservative treatment during the original acute hospital admission. In all patients the course of the disease dictated a surgical approach. Morbidity was 71.1% and the in-hospital mortality rate was 16.7%. Audit was done by comparing observed mortality with the POSSUM predicted mortality in risk scales of increased mortality. Factors leading to a higher morbidity or mortality risk were identified. In deceased patients possible management failures were investigated.

Patients who developed complications were older, needed more and sometimes multiple re-operations, and had a higher Physiological Score (PS). No relation between morbidity and gender, indication for surgery, Hinchey classification or type of surgery was found. Non-survivors were older, suffered complications more frequently, and suffered more than one complication. Non-survivors had higher Physiological Scores, suffered more pulmonary and cardiac complications and developed sepsis, and ultimately multiple organ failure, more frequently. In this series there was no significant difference in mortality between patients classified as having a Hinchey I-II or Hinchey III-IV classification. A mortality of 13.4% was found in patients with a Hinchey I-II classification and this was high when compared with the literature. It was concluded that differences in definition of indications for acute surgery, lack of information on how ill these patients were when they came to surgery i.e. lack of proper patient risk stratification, could explain the observed difference. The observed mortality for patients with a Hinchey III-IV classification was 21.3% and this corresponded well with a reported mortality rate of 21.4%. After stratification in risk groups the POSSUM system was correct in the lowest risk groups but overpredicted mortality by a factor 2 in the highest risk group. In three deceased patients possible management failures were identified and definite management failures were found in two deceased patients. However preoperative co-morbidity was usually very significant in deceased patients. Reversal of the Hartmann's procedure as a secondary procedure was undertaken in 57 out of 62 surviving patients (91.9%). This was successful in 56 patients and in one patient continuity could not be restored. Two patients died from postoperative complications. At follow-up 8 patients of the surviving 88 patients had a permanent colostomy.
It was concluded that acute complications of diverticular disease of the sigmoid colon that need surgical treatment carry a high morbidity rate and a substantial mortality rate. This study has also shown that to a large extent mortality and morbidity is driven by patient related factors as expressed by elevated physical severity scores, increased co-morbidity, and lack of peri-operative management failures in the majority of deceased patients.

The outcome of patients who survived after a primary acute or elective Hartmann's procedure for complicated diverticulitis is described in **chapter 4**. Over a 12-year period, 91 consecutive patients underwent a primary Hartmann's procedure. Of these patients 72 survived longer than 3 months after discharge of whom sixty-five underwent an attempted reversal after Hartmann's procedure. In 63 patients (96.9%) bowel continuity could be restored with a morbidity of 38.5% and a mortality rate of 3.1%. Complications were associated with older age and a higher Physiological Score (PS). Women suffered more urinary tract

complications than men. Postoperative complications are described extensively. Deceased patients had suffered multiple complications more frequently than survivors but otherwise no differences between survivors and nonsurvivors regarding gender, age, Physiologic Score, or Operative Severity Score were found. Four groups of patients defined by increasing POSSUM predicted mortality rates were examined. Predicted mortality was compared with the observed mortality rate in each group. The POSSUM score adequately predicted the observed mortality rate.
It was concluded that when surgical treatment for complicated diverticular disease of the sigmoid colon is necessary the Hartmann procedure may still be a useful solution. Contrary to what is stated in the literature Hartmann's procedure may be restored in the majority of patients who survive their primary operation.

It is not known whether results are different when surgeons perform an operation for different indications. In **chapter 5** the outcome of elective sigmoid resection for carcinoma or complicated diverticulitis are compared. The POSSUM, p-POSSUM, and cr-POSSUM scoring systems were used for risk-adjustment. We also investigated whether in this subgroup analysis recalibration of the original POSSUM equation was necessary. Over a period of 12 years a consecutive series of 241 patients were studied. Out of these, 120 patients suffered from adenocarcinoma, and 121 patients suffered from complicated diverticulitis. Patients with an adenocarcinoma of the sigmoid colon were older, had higher PS (Physiological Score) and higher OSS scores (Operative Severity Score) than patients with complicated diverticulitis. Observed mortality for patients with an adenocarcinma of the sigmoid colon was lower, but not significantly so, than for patients with complicated diverticulitis. In contradistinction the POSSUM, p-POSSUM and cr-POSSUM predicted mortalities were higher in patients with adenocarcinoma of the sigmoid colon. The overall POSSUM predicted mortality was 8.4%, being 10.6% in patients with adenocarcinoma of the sigmoid colon and 6.3% in the patients with complicated diverticulitis. When the p-POSSUM equation was used, the predicted mortality rate was 3.0% overall, being 3.8% for patients with adenocarcinoma of the sigmoid colon and 2.2% for patients with complicated diverticulitis The cr-POSSUM predicted an overall mortality of 3.0%, being 3.8% for patients with adenocarcinoma of the sigmoid colon and 2.3% for patients with complicated diverticulitis.
After elimination of the score for carcinoma from the OSS and the cr-OSS and replacing it with the score for no malignancy, mortality rates were re-calculated. Predicted mortality (overall, patients with adenocarcinoma, patients with complicated diverticulitis) were as follows: POSSUM (6.8%, 7.3% and 6.3%), p-

POSSUM (2.4%, 2.7% and 2.2%), and cr-POSSUM (2.7%, 3.1% and 2.3%). In our series, the POSSUM formula overpredicted mortality in all groups while the p-POSSUM and cr-POSSUM equations slightly overpredicted mortality in patients with adenocarcinoma, slightly underpredicted mortality in patients with complicated diverticulitis, but adequately predicted overall mortality. Eliminating the score for malignancy and replacing it with the minimum score of 1 gave overall O: E death ratios of 0.37 (POSSUM), 1.04 (p-POSSUM), and 0.93 (cr-POSSUM). This would suggest that diverticular disease of the simoid colon, much more than adenocarcinoma, may be a major factor in the origin of morbidity and mortality after resection of the sigmoid colon.
It was concluded that recalibration of the original POSSUM equilibration may be necessary in subgroup analysis.

In chapter 6 the relation specialization and training, and improved outcome of surgery is analysed. The aim of the Dutch national TME trial was to reduce the numbers of local recurrence by having well-trained and specialized surgeons operate on all patients. Teaching sessions, tutor assisted surgery and quality control formed an integral and important part of the trial. We wondered if this nationwide training and specialization, as a side effect, changed the surgical practice regarding the use of abdomino-perineal resection and low anterior resection in The Netherlands and whether changes in surgical practice affected postoperative hospital mortality rates for abdomino-perineal resection and low anterior resection. From 1994-99, 15978 patients underwent either an abdomino-perineal resection (APR; n=2575) or low anterior resection and anastomosis (n=13403) in The Netherlands. The Dutch TME trial started in 1996. A total of 1530 patients were included by 83 hospitals and 82.1% of these patients were included from 1997 to 1999. Therefore two equal periods were created: period I included patients operated in 1994-1996 and period II included patients operated in 1997-1999. Three groups of participating hospitals were studied: university hospitals, peripheral hospitals with training facilities, and non-training peripheral hospitals. Patients operated in the university hospitals were significantly younger. In each period and for each type of hospital the APR ratio was calculated. The APR ratio was defined as number of APR's divided by the number of all rectal resections (APR and Low anterior resection). Between period I and period II the APR ratios declined significantly. This was caused by a decline in APR ratio in peripheral hospitals with or without training facilities. The increase in number of low anterior resections (lower APR ratio) performed was not accompanied by an increased in-hospital mortality rate for either hospital group.

It was concluded that the effects of differentiation caused by the Dutch TME trial improved the quality of outcome of rectal surgery.

The hospital variation in postoperative mortality after colorectal resections in The Netherlands was studied in chapter 7. The influence of a risk model, based on multilevel logistic regression analysis, on the ranking of hospitals was also studied. This study used a large administrative database that was collected by hospital-based registries. Data fields used in this study were gender, age (only adults), acute or elective surgery and type of operation. As well as, discharge alive or in-hospital death, hospital number (anonimised), hospital category (university hospital, teaching hospital, or general hospital), year of surgery (from 1994 through to 1999), and hospital volume. Patients undergoing local rectal resection, pull through operations, and (sub-) total colectomy were excluded. The data were obtained from the Dutch central data registry (Prismant). The validity of these data has been the subject of a large national study. Good correlation was found between the administrative data and feedback obtained from the treating surgeon especially in those patients that underwent a surgical procedure. A correct administrative coding was obtained in over 95% of patients. For example in the hospital of the author there was complete agreement between mortality numbers and only 0.4% difference in the number of colorectal resections performed. Hospitals were divided into numbers of patients treated during the study period; low volume (1-540 patients), intermediate volume (541-773 patients) and high volume (>773 patients) hospitals. There were 69 low volume hospitals that each treated an average of 54 patients a year, 36 intermediate volume hospitals that treated 106 patients and 23 high volume hospitals that treated 162 patients each year. Multilevel logistic regression analyses were carried out with death (yes/no) as the response variable and as independent variables the categorical variables: type of hospital (university, teaching, and general), total number of procedures per hospital (low, intermediate or high), urgency of surgery (yes/no), gender and age (20-49, 50-69, 70-79 and 80+ years). First level variables were: age, gender and urgency of the opertion. Second level variables were volume and type of hospital. Overall in-hospital mortality was 7.0 %. Some 3.9 % of patients died after elective procedures and 14.3 % died after acute operations. Mean age and acute/elective ratio were equal in all hospital volume groups and mean crude mortality rate was, although not significantly, lowest in the low volume hospitals. Acute operation (odds ratio = 3.89) and age (odds ratio's for 50-69, 70-79, > 80 age groups compared to the <50 age group were: 2.63, 5.23, 10.13) were the strongest effects followed by male sex (odds ratio = 1.48) and type of hospital. Hospital volume was not a predictive factor.
It was concluded that advanced age and acute mode of surgery are by far the

most important factors related to postoperative mortality after colorectal resections. Other less important independent factors are male sex and teaching status of hospitals. Hospital volume is not a predictor of postoperative mortality after colorectal resections in the Netherlands.

Chapter 9

SAMENVATTING EN CONCLUSIES

In dit proefschrift worden de resultaten beschreven van een aantal vormen van colorectale chirurgie en worden risicofactoren, die de kans op postoperatieve complicaties en sterfte bepalen, onderzocht en geïdentificeerd.

HOOFDSTUK 1

In de algemene introductie worden, in paragraaf 1, de verschillende methodes beschreven en becommentarieerd die in de Verenigde Staten van Amerika, het Verenigd Koninkrijk en in Nederland worden gebruikt om de resultaten van chirurgie te verbeteren, te toetsen of onderling te vergelijken.
Toenemende interesse van verzekeraars en werkgevers in de uitkomst van zorg, het Leapfrog-initiatief, leidde in de Verenigde Staten tot de discussie of er een verband is tussen de uitkomst van zorg, het aantal ingrepen en de ervaring van zowel het ziekenhuis als van de chirurg. Deze discussie staat in het Verenigd Koninkrijk minder op de voorgrond, maar daar ligt het zwaartepunt vooral op het ontwikkelen van scoringssystemen die voor een patient het risico kunnen voorspellen om na een operatie complicaties te krijgen of hieraan te overlijden. In Nederland werd voor oesophagus- en pancreascarcinoom onderzoek verricht naar de relatie tussen de uitkomst en het aantal operaties per ziekenhuis. Verder werden in Nederland landelijke trials uitgevoerd bij patiënten met maag- of rectumcarcinoom waarbij uitgebreide aandacht werd besteed aan coaching en kwaliteitscontrole. Hierdoor werden meer van deze patiënten door gespecialiseerde chirurgen geopereerd met vermoedelijk een betere uitkomst.
Geconcludeerd wordt dat er enige aanwijzingen zijn dat er bij colorectale chirurgie een verband is tussen specialisatie, ziekenhuisvolume en chirurgvolume enerzijds en de uitkomst van zorg anderzijds, maar dat betrouwbare toetsing en vergelijking alleen mogelijk is op basis van mortaliteitcijfers die zijn gecorrigeerd op patiëntensamenstelling, hun risicoprofielen en na controle van de betrouwbaarheid van de diverse gegevens.

In de tweede paragraaf van dit hoofdstuk wordt de database, die de basis vormt voor de meeste studies in dit proefschrif, beschreven en gevalideerd.
De grove complicatie- en sterftecijfers worden vermeld van 1604 patiënten die tussen 1990 en 2002 in de Zaanstreek werden geopereerd aan het colon of rectum.

Het systeem dat werd gekozen voor risicoanalyse, de POSSUM-systematiek

(Physiologic and Operative Severity Score for the enUmeration of Mortality and morbidity), wordt uitgebreid besproken in de derde paragraaf. In de beschreven database wordt de POSSUM-voorspelde mortaliteit vergeleken met de geobserveerde sterfte.
De voorspellende waarde van de met de verschillende POSSUM-formules berekende sterftecijfers blijkt beperkt en is mede afhankelijk van de risicogroep waarin de patient zich bevindt. Ook zijn er aanwijzingen dat POSSUM-modellen regio- en onderwerpspecifiek moeten zijn.
Geconcludeerd wordt dat vooral de risicofacoren in het scoringssystem bruikbaar zijn bij risicoanalyses en toetsing en dat, zolang er geen betere modellen zijn ontwikkeld, de POSSUM- en p-POSSUM-modellen de standaard moeten zijn waaraan nieuwere systemen worden getoetst.

In de vierde paragraaf van hoofdstuk 1 worden de hoofdlijnen van dit proefschrift beschreven.

HOOFDSTUK 2

Van 149 patiënten, die een primaire electieve operatie ondergingen voor divertikelziekte van het sigmoid, worden de resultaten gegeven. De postoperatieve complicaties en mortaliteitcijfers worden beschreven en er wordt onderzocht welke risicofactoren uit het POSSUM-scoringssysteem een relatie hebben met een verhoogde kans op complicaties of postoperatieve sterfte. De gevonden mortaliteit werd getoetst aan de door de POSSUM-systematiek voospelde sterfte in verschillende risicoschalen. Voorts werd gekeken naar mogelijke fouten in het perioperatieve beleid. De operatieindicaties werden gesteld volgens de richtlijnen van het “American College of Gastroenterology” en “The American Society of Colon and Rectal Surgeons” en waren als volgt. Fistels (n =28): colovesicale fistels (n = 25); coloenterovesicale fistels (n =1); colovaginale fistels (n = 2). Recidiverend aanvallen van diverticulitis zonder septische complicaties (n = 59). Diverticulitis met septische complicaties (n = 6): waaronder leverabces (n =2), colisepsis (n =1) en abces in het kleine bekken (n =3). Functionele klachten (n =22). Bloeding (n =2) of stenosis met of zonder verdenking op maligniteit (n = 32). Bijna 54 procent van de patiënten kreeg complicaties. Vrouwen kregen significant meer urineweginfecties, mannen meer intra-abdominale abcessen en reoperaties. Patiënten die overleden, hadden significant meer intra-abdominale abcessen, naadlekkages, luchtweginfecties, thrombo-embolie, cardiale complicaties en sepsis. Significant meer complicaties werden gevonden bij patiënten met een hogere “Physiological POSSUM score” (PS), die veroorzaakt werd door afwijkingen in bloeddruk, polsfrequentie en het haemoglobine-gehalte. Er was geen verband tussen deze complicaties en de “Operative Severity POSSUM Score” (OSS). Zeven

(4.7%) van de 149 patiënten overleden postoperatief in het ziekenhuis. Zij bleken een significant hogere PS en OSS te hebben. Deze werden in de PS veroorzaakt door een hogere leeftijd, afwijkingen in de polsfrequentie alsmede afwijkingen in het haemoglobine gehalte, het aantal leucocyten en het ureum-, natrium- en kaliumgehalte in het bloed. In de OSS waren het de factoren: meerdere procedures en het peroperatieve bloedverlies. De POSSUM-vergelijking bleek de mortaliteit in de hoge risicogroepen goed te voorspellen maar niet in de lage risicogroepen. Onderzoek in de groep patiënten die overleed naar mogelijke fouten in het perioperatieve beleid liet zien dat bij mogelijk drie patiënten een ander beleid tot een betere resultaat geleid zou kunnen hebben.
Conclusie: Na een operatie voor niet-acute complicaties van diverticulosis van het sigmoid is er een aanzienlijke kans op complicaties of postoperatieve sterfte. Een verhoogde kans op complicaties of sterfte wordt voornamelijk bepaald door patient- en ziektegebonden factoren.
Bij toetsing en vergelijking dienen deze factoren dan ook te worden meegenomen in de beoordeling van mortaliteitcijfers.

HOOFDSTUK 3

Het doel van deze studie is het vaststellen van de kans op complicaties en postoperatieve sterfte na een primaire acute operatie voor complicaties van sigmoiddiverticulitis en de identificatie van patient- en ziektegebonden risicofactoren die leiden tot een grotere kans op postoperatieve complicaties of mortaliteit. Gedurende een aaneengesloten periode van twaalf jaar werden 114 patiënten geopereerd voor een perforatie-peritonitis (n =62), obstructie ileus (n =24) of een dermate mislukte conservatieve therapie, dat tijdens de acute ziekenhuisopname een operatie noodzakelijk werd (n =28). Bij de onderzochte groep patiënten werden de ernst van de diverticulitis en de patientgebonden risicofactoren nauwkeurig omschreven. De factoren uit de POSSUM-systematiek werden gebruikt voor de risicoanalyse. Er werd bij 81 (71.1%) patiënten een Hartmann-procedure verricht, bij 21 (18.4%) een resectie met primaire anastomose en bij 12 (10.5%) werd alleen een colostoma aangelegd. Bij 71.1 procent van de patiënten traden complicaties op. Complicaties en hun frequentie worden voor de hele groep beschreven alsmede uitgesplitst voor de overleden en niet overleden patiënten. De postoperatieve sterfte was 16.7 procent. Patiënten die overleden hadden significant meer: meerdere complicaties, luchtweginfecties, cardiale complicaties, sepsis en multiple organ failure. Risicofactoren die leidden tot een significant grotere kans op complicaties en sterfte waren leeftijd en een hogere PS (Physiological Score). De Hinchey-classificatie bleek geen relatie te hebben met de kans op complicaties of mortaliteit.
In vergelijking met de literatuur leek de mortaliteit in de Hinchey-groep I-II (13.4

%) hoog. Vergelijking van deze groep is echter niet goed mogelijk wegens het gebrek aan informatie over patientgebonden risicofactoren, morbiditeit en de definitie van acute chirurgie in de literatuur. De POSSUM-voorspelde mortaliteit kwam in deze Hinchey-groep ongeveer overeen met de geobserveerde. De sterfte in Hinchey-groep III-IV (21.3%) kwam wél overeen met de literatuur. POSSUM voorspelde echter een tweemaal hogere mortaliteit in deze categorie. Ook indien werd gestratificeerd op basis van de POSSUM-voorspelde mortaliteit vond de POSSUM-vergelijking in de hoogste risicogroep een tweemaal hogere sterfte dan die welke in deze groep geobserveerd werd. Bij twee overleden patiënten werden fouten gevonden in de perioperatieve zorg, bij drie anderen zou het beleid wellicht anders geweest moeten zijn, maar bij de meeste overleden patiënten was er ernstige co-morbiditeit, die de kans op postoperatieve sterfte sterk vergrootte. Bij 57 van de 62 patiënten die een Hartmann-procedure overleefden werd een hersteloperatie verricht. Dit geschiedde bij 56 patiënten met succes, waarvan twee patiënten overleden aan de ingreep. Bij één patient kon de continuïteit niet worden hersteld. Uiteindelijk hielden 8 van de in totaal 88 overlevende patiënten een permanent stoma.
Conclusie: Deze studie toont aan, dat er na een acute operatie voor sigmoiddiverticulitis een grote kans bestaat op complicaties en mortaliteit. Deze blijkt vooral te worden bepaald door patientgebonden factoren, zoals blijkt uit een hogere PS en weinig fouten in het perioperatieve beleid met betrekking tot de overleden patiëntengroep.
De Hinchey-classificatie heeft geen voorspellende waarde voor de kans op postoperatieve complicaties of sterfte.

HOOFDSTUK 4

De beslissing welke operatie moet worden verricht, behoort gebaseerd te zijn op betrouwbare gegevens. In dit hoofdstuk wordt de uiteindelijke uitkomst onderzocht van alle patiënten die overleefden na een Hartmann-procedure voor gecompliceerde diverticulitis. In een aaneengesloten periode van twaalf jaar werd bij 91 patiënten een acute of electieve Hartmann-procedure verricht voor gecompliceerde sigmoiddiverticulitis. Hiervan overleefden 72 patiënten langer dan drie maanden na ontslag uit het ziekenhuis waarvan 65 patiënten opnieuw werden geopereerd met het doel om de Hartmann-situatie op te heffen. Bij 63 (96.9%) patiënten kon de continuïteit worden hersteld, bij twee bleek dit technisch niet mogelijk. Het complicatiepercentage was 38.5 procent. Patiënten met complicaties waren significant ouder en hadden een significant hogere "POSSUM Physiological Score"(PS). Complicaties en de frequenties ervan worden vermeld. Twee (3.1%) patiënten overleden postoperatief. Deze bleken significant meer multipele complicaties te hebben maar verder was er geen verband aan

te tonen tussen sterfte en geslacht, leeftijd, PS, of "POSSUM Operative Severity Score" (OSS). De POSSUM- en de p-POSSUM-formules bleken de geobserveerde sterfte adekwaat te voorspellen.
Conclusie: Dit onderzoek laat zien dat een Hartmann-procedure nog steeds een goede oplossing is indien een operatie voor ernstig gecompliceerde diverticulitis nodig is.
In een hoog percentage van de patiënten kon de continuïteit van het colon weer worden hersteld met een acceptabele postoperatieve sterfte welke op adekwate wijze door de POSSUM- en p-POSSUM-formules werd voorspeld.

HOOFDSTUK 5

In een groep patiënten die een electieve sigmoidresectie voor carcinoom of divertikelziekte ondergingen, werd de mortaliteit vergeleken met de mortaliteit zoals die wordt voorspeld met de POSSUM-formule (Physiologic and Operative Severity Score for the enUmeration of Mortality and morbidity), de p-POSSUM-formule (Portsmouth-POSSUM) en de cr-POSSUM-formule (colorectale-POSSUM). Risicofactoren die de kans op complicaties en postoperatieve sterfte vergroten, werden geïdentificeerd. Verder werden verschillen tussen de carcinoom- en divertikelgroep in kaart gebracht. In de periode 1990 t/m 2001 werden 241 patiënten geopereerd waarvan 120 met een carcinoom en 121 met divertikelziekte van het sigmoid. Patiënten met een carcinoom hadden een significant hogere "Physiological Score" (PS) en "Operative Severity Score" (OSS). Deze werden veroorzaakt door een hogere leeftijd en een lager Hb-gehalte in het bloed in de PS en een hogere score voor maligniteit in de OSS.
Bij 47.7 procent van de patiënten deden zich complicaties voor. Een hogere leeftijd, PS, cr-PS of cr-OSS ging gepaard met een grotere kans op complicaties. Er was geen verschil in complicaties tussen de carcinoom- en diverticulosegroep. In de hele groep was de postoperatieve sterfte 2.5 procent (carcinoomgroep 1.7%, diverticulose groep 3.3%)
Patiënten die overleden, bleken significant meer dan een primaire operatie te hebben ondergaan en hadden een hogere PS en cr-PS ten gevolge van een lager Hb, een hoger ureum- of een afwijkend natriumgehalte in het bloed. Het verschil in sterfte tussen de carcinoomgroep en de diverticulosisgroep bleek niet significant. De totale POSSUM-voorspelde mortaliteit was 8.4 procent (carcinoom: 10.6 %, diverticulosis 6.3 %). Bij toepassing van de p-POSSUM-formule en de cr-POSSUM-formule was dit respectievelijk 3.0 procent (carcinoom: 3.8 %, diverticulosis 2.2 %) en 3.0 procent (carcinoom: 3.8%, diverticulosis 2.3 %). Indien in de verschillende POSSUM-formules de score voor maligniteit werd vervangen door die voor niet-maligniteit, werden de volgende percentages gevonden: POSSUM: 6.8 procent (carcinoom 7.3 %, diverticulosis 6.3 %), p-POSSUM: 2.4 procent (carcinoom: 2.7 %,

diverticulosis 2.2 %) en cr-POSSUM: 2.7 procent (carcinoom: 3.1 %, diverticulosis: 2.3 %). De POSSUM-voorspelde mortaliteit was te hoog in alle groepen. De p-POSSUM- en cr-POSSUM-formules waren gelijkwaardig, want beide voorspelden de mortaliteit in de carcinoom groep iets te hoog en in de diverticulosisgroep iets te laag.

Indien de score voor carcinoom werd vervangen door de diverticulosisscore waren de resultaten nog beter in overeenstemming met "overall observed: expected ratios" van 1.04 (p-POSSUM) en 0.93 (cr-POSSUM).

Conclusie: in de hier besproken subgroepanalyse werd gevonden dat bij patiënten, die een electieve resectie van het sigmoid ondergaan voor carcinoom of divertikelziekte, de mortaliteit kan worden voorspeld met zowel de p-POSSUM- als met de cr-POSSUM-systematiek, in het bijzonder als daarbij maligniteit niet extra wordt gescoord.

Hoewel bij de carcinoompatiënten significant meer risicifactoren bestonden, was de mortaliteit in deze groep, hoewel niet significant, lager dan in de diverticulosisgroep.

Dit kan betekenen dat divertikelziekte van het sigmoid, eerder dan een carcinoom, een factor is die leidt tot een hoger operatierisico.

HOOFDSTUK 6

Het lijkt aannemelijk dat er een verband bestaat tussen de resultaten van colorectale chirugie en ziekenhuisvolume, chirurgvolume of specialisatie. Een van de voorwaarden voor deelname aan de "Dutch TME trial" (TME: Total Mesorectal Resection bij rectumresecties voor carcinoom) was dat de operatie werd verricht door speciaal hiervoor opgeleide chirurgen. Deze opleiding bestond uit: training en coaching door op TME gebied ervaren chirurgen. Tevens vonden kwaliteitscontroles plaats. Onderzocht werd of, als bijproduct van deze trial, naast reductie van het aantal lokaal recidieven, een verschuiving optrad in de verhouding tussen het aantal rectumamputaties en het aantal anteriorresecties. En, zo ja, of dit van invloed was op de postoperatieve sterfte. In de periode 1994 t/m1999 werd in Nederland bij 15,978 patiënten een rectumresectie verricht. In 2,575 gevallen werd een abdominoperineale rectumamputatie (APR) verricht en13,403 keer een anteriorresectie. De "Dutch TME trial" werd in 1996 gestart. Door 83 deelnemende ziekenhuizen werden 1,530 patiënten ingebracht, waarvan 82.2 procent in de jaren 1997 t/m 1999. Om het effect van de studie te meten werden twee periodes gekozen. Periode I bevatte de patiënten die werden geopereerd van 1994 t/m 1996; periode II liep van 1997 t/m 1999. De deelnemende ziekenhuizen werden verdeeld in universiteitsziekenhuizen (n =7), perifere opleidingsziekenhuizen (n =34) en perifere niet-opleidingsziekenhuizen (n =67). Per periode werd voor elk soort

ziekenhuis de APR ratio berekend, welke gedefinieerd werd als het aantal APR's gedeeld door het totaal aantal rectumresecties. In periode II bleken de APR ratios significant gedaald te zijn in de hele groep ziekenhuizen (van 0.19 naar 0.13). Deze daling kwam geheel op rekening van de perifere opleidingsziekenhuizen (van 0.22 naar 0.14) en de perifere niet-opleidingsziekenhuizen (van 0.17 naar 0.12). In de universitaire centra was er geen verandering (van 0.20 naar 0.20). Oorzaak hiervan kan zijn dat er in de academische ziekenhuizen al eerder een omslag was in de APR ratio, of dat meer patiënten die een APR nodig hadden naar hen werden verwezen.
De sterftepercentages veranderden niet significant. De totale postoperatieve sterfte in periode I en II bedroeg respectievelijk 3.5 procent en 3.7 procent. Voor de universiteitsziekenhuizen was dit 2.8 procent en 1.8 procent, voor de perifere opleidingsziekenhuizen 3.4 procent en 4.0 procent en voor perifere niet-opleidingsziekenhuizen 3.6 procent en 3.8 procent. De lagere sterfte in de universitaire centra kan deels worden verklaard door de significant lagere leeftijd van de daar behandelde patiënten.
Conclusie: de "Dutch TME trial" verbeterde de kwaliteit van de rectumchirurgie in Nederland. Er werden significant meer anastomoses gemaakt en er ontstonden minder lokaal recidieven bij een gelijkblijvende mortaliteit.

HOOFDSTUK 7

In dit hoofdstuk worden de verschillen in postoperatieve sterfte na colorectale chirurgie tussen de Nederlandse ziekenhuizen bestudeerd. Tevens worden factoren gekwantificeerd die leiden tot een grotere kans op mortaliteit. Vervolgens wordt aangetoond dat, via "multilevel logistic regression"(MLR) analyse met een aantal risicifactoren -waarvan wordt verondersteld dat zij een verhoogde sterftekans geven- een betrouwbare ranglijst van ziekenhuizen opgesteld kan worden. In de statistische analyse werd de variabele "overleden" (ja/nee) gezet tegenover de onafhankelijke categorale variabelen "level 1": urgentie (acuut/niet acuut), geslacht (man/vrouw) en leeftijd (20-49, 50-69, 70-79 of 80 jaar en ouder) en "level 2": soort ziekenhuis (universitair: n =8, opleidingsziekenhuis: n =37 of algemeen ziekenhuis: n =83) en volume van het ziekenhuis (laag: 54 resecties per jaar, gemiddeld: 106 resecties per jaar en hoog: 162 resecties per jaar). De variabele "urgentie" werd als acuut gedefinieerd indien de operatie binnen 24 uur na een acute opname werd verricht. De benodigde gegevens werden verkregen via Prismant. De betrouwbaarheid van de Prismant-gegevens werd aangetoond in een landelijke studie. Bij vergelijking van de Prismant-getallen met onze colorectale database bleek de mortaliteit exact gelijk te zijn en het aantal ingrepen 0.4 procent te verschillen.
Alle volwassenen (n =67,594) die tussen 1994 en 1999 een primaire colorectale

resectie ondergingen, werden in deze studie opgenomen (lokale excisies, pullthrough operaties en (sub-)totale colectomieën uitgezonderd). Er waren 19,981 (29.6%) acute en 47,613 (70.4%) electieve procedures. Partiële colectomieën bij 48,240 (71.4%) patiënten en rectumresecties bij 19,354 (28.6%). De totale postoperatieve ziekenhuissterfte was 7.0 procent (electief: 3.9%, acuut 14.3%). Hoewel de gemiddelde leeftijd en de verhouding acuut/niet acuut in alle ziekenhuisvolumegroepen gelijk was, bleken de laagvolumeziekenhuizen de laagste ruwe sterftecijfers te hebben. Na statistische analyse bleken van de variabelen leeftijd (odds ratio 2.63, 5.23 en 10.17 voor de leeftijdsgroepen 50-69, 70-79 en 80 of ouder) en urgentie (odds ratio 3.89) veruit de grootste invloed te hebben op de postoperatieve sterfte. Gevolgd door mannelijk geslacht (odds ratio 1.48). Het ziekenhuistype was minder belangrijk waarbij opleidingsziekenhuizen (odds ratio 0.74) en algemene ziekenhuizen (0.62) beter presteerden dan de academische (odds ratio 1). Het ziekenhuisvolume had nauwelijks invloed (odds ratios: laagvolume 1.0, gemiddeldvolume 1.12 en hoogvolume 1.16). Nadat alle interacties in het statistische model waren ingevoerd, kon een ranglijst worden opgesteld waarin negen ziekenhuizen significant slechter presteerden dan gemiddeld en twee beter. Vergelijking met een ranglijst gebaseerd op ruwe mortaliteitcijfers liet een compleet andere volgorde zien, waarbij ruim 60 procent van de ziekenhuizen meer dan 10 plaatsen verschoven en 40 procent meer dan 25 plaatsen. Een ziekenhuis kon 72 plaatsen hoger of 61 lager komen te staan.

Conclusie: aangetoond werd dat er tussen de Nederlandse ziekenhuizen onderling weinig verschil is in sterftecijfers na colorectale chirurgie. De leeftijd en een acute operatie zijn de belangrijkste factoren voor een verhoogde kans op postoperatieve sterfte. Minder belangrijk zijn mannelijk geslacht en type ziekenhuis. Ziekenhuisvolume is geen voorspellende factor bij de sterftekans na colorectale operaties. Indien ranglijsten worden opgesteld, dienen ruwe mortaliteitcijfers gecorrigeerd te worden voor de risicofactoren.

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CURRICULUM VITAE

J.L.T. Oomen (Hans) werd op 18 oktober 1943 geboren te Nieuwer-Amstel (thans Amstelveen). Na de lagere St. Antoniusschool te Amstelveen werden de eerste drie jaar van de HBS-b doorlopen op het Thomas Moore college van het internaat Saint Louis te Oudenbosch en de laatste twee op het Sint Nicolaas lyceum te Amsterdam.

Hij studeerde Geneeskunde aan de Universiteit van Amsterdam en behaalde in 1970 het artsdiploma. Na vervulling van de militaire dienstplicht als officier-arts werd hij van 1 september 1971 tot 1 september 1977 tot algemeen chirurg opgeleid in het Onze Lieve Vrouwe Gasthuis te Amsterdam met als opleiders Dr. P.R. Pinxter en Dr. J.R. Borggreve.

Sinds september 1977 werkt hij als algemeen chirurg in Zaanstad, eerst in het Juliana Ziekenhuis, na de fusie met het Johannes Ziekenhuis in het Zaans Medisch Centrum.

Zijn ouders zijn L.A.A. Oomen† en P.E.M. Appelboom.
Hij is gehuwd met Sheila Beijer. Zij hebben één zoon, Marcel Hans.